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THE CAROLINA
JOURNAL of PHARMACY

JANUARY, 1986 VOLUME 66 NUMBER 1

UNIVERSITY of NORTH CAROLINA

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Late Spring — 1951

Appearing in the picture are members of the NCPA executive committee, who met on September 5th, Auxiliary representatives and guests. The group has the distinction of being the first to meet in the Institute of Pharmacy.

THE NORTH CAROLINA INSTITUTE OF PHARMACY FROM DREAM TO REALITY

By W. J. Smith
Executive Director Emeritus

Presented at the Fall Convocation of the Woman's Auxiliary of the North Carolina Pharmaceutical Association, October 9, 1985.

BACKGROUND

The North Carolina Pharmaceutical Association was organized in Raleigh, on August 11, 1880. Edward M. Nadal of Wilson was elected President, and Dr. T.C. Smith of Charlotte, Secretary.

Officers of the NCPhA rotated from year to year until 1912 when John Grover Beard of Chapel Hill, a staff member of the UNC School of Pharmacy, was named Secretary of the Association.

For the next twenty-eight years, Professor Beard (appointed Dean of the UNC School of Pharmacy in 1931) served in dual posts with the School and the NCPhA until his resignation in 1940. The executive office of the NCPhA was located at the School of Pharmacy (Howell Hall).

On July 1, 1921, Miss Alice Noble began her long association with North Carolina Pharmacy as Assistant Secretary to the UNC School of Pharmacy as well as Associate Secretary of the NCPhA. This position included assisting Dean Beard in editing and mailing the *Carolina Journal of Pharmacy.*

NCPhA EMBARKS ON NEW ERA

Following Dan Beard's resignation in 1940 as Secretary-Treasurer of the NCPhA, the Association's Executive Committee took action to convert the post from part-time to full-time. W.J. Smith, a 1937 graduate of the School of Pharmacy and employed in a pharmacy in Hickory was interviewed and hired. On June 20, 1940, Pharmacist W.J. Smith assumed the positions of Secretary-Treasurer of the NCPhA and Managing Editor of the *Carolina Journal of Pharmacy.*

Compensation was set at $175 per month plus travel costs. Since the NCPhA was not in position to pay this expense, an agreement was negotiated with the N.C. Board of Pharmacy whereby Smith would work part-time as one of the state's two pharmacy inspectors. This arrangement continued until the financial position of the NCPhA improved to the point where the Association could assume complete financial responsibility for its operation.

OFFICE LOCATES IN HOWELL HALL

Since the headquarters of the NCPhA had been located in the dean's office at Howell Hall for nearly thirty years, the School of Pharmacy's generous offer to continue to provide space to W.J. Smith was gratefully accepted by the Association's Executive Committee.

A basement room in Howell Hall, previously used for storage of books, was vacated, cleaned, and repainted. When W.J. Smith moved into the room, he was unaware he would be a guest of the University of North Carolina for the next ten years.

In 1940, when the new NCPhA office was established, NCPhA-owned equipment being used in Howell Hall was transferred to W.J. Smith. This equipment consisted of a hand operated Addressograph with member plates, a wooden 5x7 card file, a financial ledger, and a bank account of $1,800. Initially, Mr. Smith's desk was a board on which was placed a self-owned $35 portable typewriter purchased second-hand from Frank Dayvault at $5 down and $5 a month. His chair was borrowed from the School of Pharmacy. There were advantages to being in the School of Pharmacy. Many pharmacy students would come by the office for coffee or conversation and these were the NCPhA members of the future. Lasting relationships were developed in that basement office.

It was from this office with its limited equipment and financial resources that the new NCPhA emerged. Of special interest at this time was membership recruitment and a concerted effort to collect current and past membership dues (some members were in arrears by as much as three years). To do this most effectively, the

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Continued from Page 5

newly selected Secretary-Treasurer set up a schedule to personally visit a majority of existing and potential members through the state. Since this involved much time away from the office — frequently Monday thru Friday — the need for an additional employee arose — someone to keep the office open, receive visitors, take telephone messages, etc.

The Secretary-Treasurer faced two problems: need of an additional staff member and no funds in the budget to pay an employee. This was solved when Vivian (Mrs. W.J.) Smith agreed to assume the post as assistant to Mr. Smith, initially without pay. From the early 1940s to her retirement in 1978, Mrs. Smith was a dedicated staff member of the NCPhA, serving in numerous capacities. By 1945, the expansion of NCPhA programs and projects demanded additional office space. At the same time, it became apparent that the School of Pharmacy needed the space occupied by the NCPhA. This set the stage for a major and ambitious project: an NCPhA-owned office building.

During the World War II years, both pharmacists and gasoline were in short supply. Eubank's Drug Store in downtown Chapel Hill was in danger of closing because of a lack of manpower, so Smith helped out as much as possible, spending his time between the basement of Howell Hall and Eubank's store. Travel was limited because of wartime gasoline rationing.

INSTITUTE OF PHARMACY — THE PLANNING STAGE

Initially, the Association's Executive Committee authorized Secretary Smith to explore the feasibility of the NCPhA undertaking the purchase of property suitable for location of an NCPhA-owned office building. At the time the committee stated any such project must be totally financed separate and apart from the NCPhA budget.

Shortly thereafter, at a meeting at the Carolina Inn in Chapel Hill, a committee of interested pharmacists endorsed the project and recommended favorable action by the Association's Executive Committee. T.J. Ham, Jr. of Yanceyville, was named Building Fund Chairman and details of a fund solicitation campaign were formulated.

The location of the NCPhA office building was decided on the basis of a mail ballot sent to all members of the NCPhA. The ballot offered

T. J. Ham, Jr. (center) is shown getting the Institute of Pharmacy Building project underway in Chapel Hill on November 2. Shown on Tom's left is NCPA president-elect J. Paul Gamble of Monroe, and on his right is W. R. (Bill) McDonald, Jr., of Hickory, president of the NCPA.

three choices: (1) Chapel Hill; (2) Raleigh; (3) Other Locations. The issue was settled when the majority of members completing the ballots designated Chapel Hill as their preference for location of the building.

This set the scene for solicitations of funds, which the NCPhA Executive Committee authorized, and for the purchase of property. The initial request for funds from the membership resulted in contributions of about $25,000, most of which came from $100 payments qualifying the donor to have his or her name on a bronze plaque to be displayed in a prominent place in the building.

In seeking land for location of the building, four potential sites were reviewed but eliminated for various reasons. Ultimately, the building committee agreed to purchase a lot in Chapel Hill, at the corner of Church and West Rosemary streets, adjacent to the original University Baptist Church. The land cost $12,500, a princely sum in those days, but today is considered a bargain.

With deed to the property, the NCPhA Executive Committee authorized employment of an architect to prepare building plans and specifications. Archie Royal Davis of Durham

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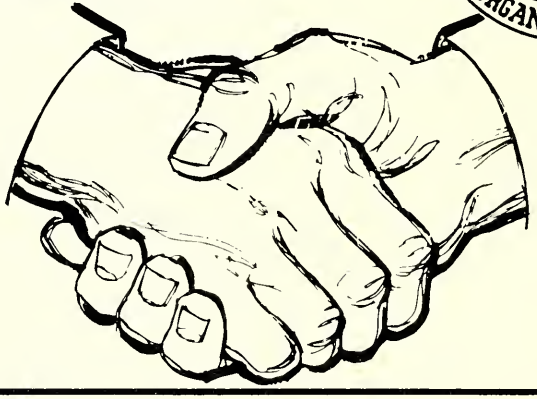

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Continued from Page 7

was retained. In order to comply with a town requirement, a Williamsburg-style building plan was prepared and approved by the Executive Committee. At the time — in the late 1940s — the town of Chapel Hill attempted to develop the western end of Chapel Hill as a "Miniature Williamsburg" but the effort did not succeed.

Interested building contractors were notified of the Association's plan for an office building and invited to submit bids. When all bids exceeded cash on hand for the project, no action was taken at that time. At this point, Ardenta Thompson, a Chapel Hill contractor with a favorable record, offered to start construction of the building in the absence of a contract. In Mr. Thompson's opinion, the building could be constructed, including all exterior doors and windows, with funds on hand. On this basis, Mr. Thompson was authorized to proceed with the project.

The ground breaking ceremony was observed in Chapel Hill on November 2, 1950. Present for the occasion were Thomas J. Ham, Jr., Chairman of the Building Committee; W.R. McDonald, Jr., NCPhA President; J. Paul Gamble, NCPhA President-Elect; the NCPhA staff, and other interested guests.

While the building was under construction, $10,00 in additional funds came in from contributors, making possible partial completion of the interior. Doors, floor coverings, air conditioning, kitchen cabinets and appliances, etc. were added as money became available.

"THE NORTH CAROLINA INSTITUTE OF PHARMACY" was occupied by the NCPhA and the North Carolina Board of Pharmacy in 1951.

THE INSTITUTE — HOW FINANCED

At one time it was estimated that more than 2,000 persons were involved in various fund-raising projects specifically earmarked for the Institute. The two pharmacy auxiliaries — Woman's Auxiliary of the NCPhA and the TMA — were in the forefront of many efforts to raise funds for the building. Many methods of raising money were used. The memorial plaque noted above eventually raised over $50,000. Auction sales at the convention, sale of standard merchandise contributed by various manufacturers (NC drug wholesalers graciously overlooked this brief activity), the trees out front were named and sold, and squares of the roof were sold in units of one square foot. At one time, fifty checks of ten dollars each were sent to members to invest for six months with the proceeds and principle to be returned to the NCPhA. One member returned almost one hundred dollars.

The W.H. King Drug Company of Raleigh contributed $5,000 in honor of its founder, B. Frank Page. Thomas Stanback of Salisbury paid for the central air conditioning, after visiting the building one very hot day.

Initially, all major appliances and furniture were sponsored by interested individuals, pharmacies and pharmaceutical manufacturers.

INSTITUTE — A CENTER OF PHARMACY ACTIVITY

The executive offices of the North Carolina Board of Pharmacy were located in the Institute of Pharmacy for many years. As a rent payer, the Board helped with some of the building's operating expenses, especially during the early days when the Association's financial condition was at a low ebb. In later years, needing additional space not available in the Institute, the Board of Pharmacy office was moved to a nearby location at Columbia and Rosemary Streets, just a block from the Institute of Pharmacy. (Note: the Board of Pharmacy is currently located in the Willow Creek Shopping Center in Carrboro).

Starting with one employee in 1940, the Association's staff has grown slowly over the years. First, the addition of Vivian Smith as an assistant to W.J. Smith. Then a janitor, Fred Cole, was added when the Institute was first occupied and Mr. Cole is still employed. Shortly thereafter, a secretary responsible for day-to-day office routine and receptionist's duties was employed. This staff position has been occupied by various persons over the years, but the record for continuity goes to Erie Cocolas, who came "temporarily" several years ago. The current staff is now five persons: Fred Cole, janitor; Laura Williams, secretary; Erie Cocolas, receptionist; and Al and Betsy Mebane. Mrs. Cocolas is in charge of membership records and correspondence; Ms. Williams processes continuing education requests and tests and Academy of Pharmacy records and handles scheduling for Mr. Mebane; and Mrs. Mebane serves as Administrative Assistant, financial secretary,

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Scenes from the Fall Convocation in the newly redecorated Institute of Pharmacy lobby.

Continued from Page 10

student loan officer and coordinator of insurance programs.

The Institute includes a 100-seat auditorium which is in constant use. For many years, the Board of Pharmacy examinations were held in this room. The Institute kitchen (equipped by the Woman's Auxiliary) is a time-saver for committee members and small groups visiting the Institute on official business. During the early days of the Institute, light lunches were served on football game days, as a means of introducing members to their new home in Chapel Hill. Since this predated the numerous restaurants and fast-food establishments now in existence, this was a welcome service to members and their guests. In some instances, more than 400 persons responded to the invitation.

THE INSTITUTE AS A POSITIVE PUBLIC RELATIONS GENERATOR

For the first decade of the Institute's existence, the building was listed as an "educational institution" by the city and county tax authorities, and therefore paid no property taxes. To compensate for this, the Institute's auditorium was made available without cost, primarily to health-related organizations, on a pre-reserved basis. The N.C. Memorial Hospital Auxiliary was organized in the Institute and scheduled its meetings here for a number of years. Two churches were organized here, and one of them used the facilities for several years for Sunday services.

The Chapel Hill Men's Garden Club, in lieu of paying rent for use of the auditorium for its monthly meetings, maintains the Institute's grounds. The Chapel Hill Rose Society also helps with the upkeep of the rose garden.

A LOOK AT THE RECORD

A complete review of the Institute's 30+ year record is impressive. A visit to the Institute produces a positive impression of Pharmacy in North Carolina, to both members and visitors.

There has been a dramatic increase in the number and scope of NCPhA programs and projects, made possible, in part, by expansion of the physical facilities. This is evident in the increased membership roll and the improved financial condition.

W.J. and Vivian Smith retired in 1978 as Executive Director and Administrative Assistant respectively. They were succeeded by Al and Betsy Mebane of Greensboro, who, with the same sense of dedication and pride in the profession, continue the Institute programs and projects as the Association heads for the year 2,000.

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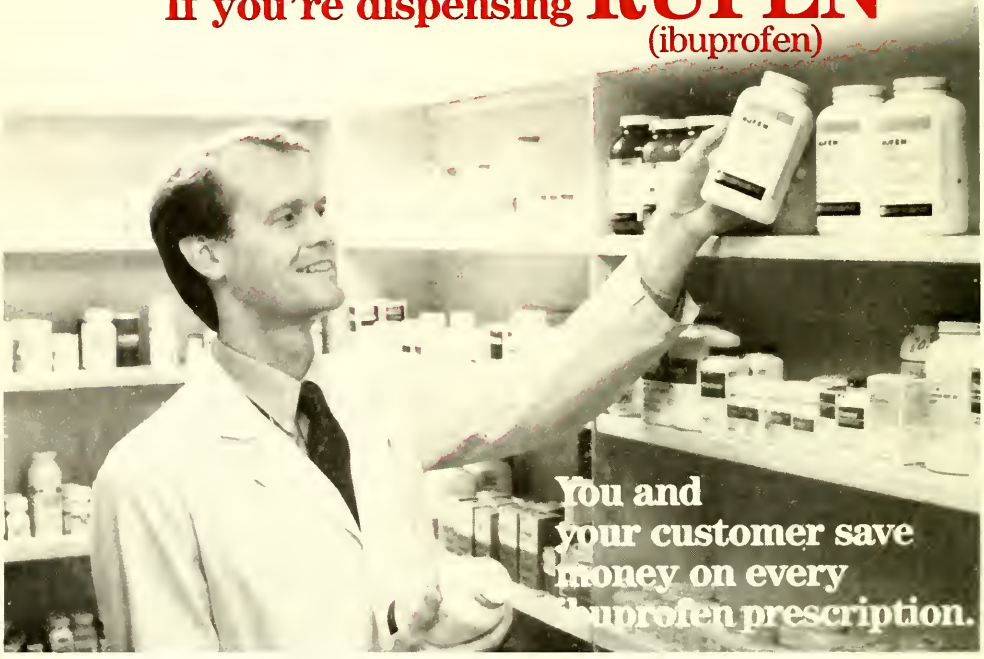

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LOCAL NEWS

The October meeting of the Charlotte Woman's Pharmaceutical Auxiliary was held at the Y. W. C. A. Mrs. Jesse Oxendine, president, presided.

Mrs. Leslie Davis, first vice president, introduced the guest speaker, Mrs. Babbs Merrill, Home Economist. Mrs. Merrill presented an interesting program on "Holiday Dinners In The Freezer". Planning is essential and management is one of the greatest aids in cooking, she said.

Mrs. Gibbs Henley, treasurer, reported that checks of $400.00 each for first semester were sent to our scholarship recipients, Lois J. Brooks, Glade Valley, N. C. and Cynthia Gay Lyerly, Salisbury, N. C. Miss Lylerly receives the Myrtle Anselment Memorial Scholarship.

Mrs. Oxendine reminded all members of the bazaar to be held in November. Proceeds will go to the scholarship fund.

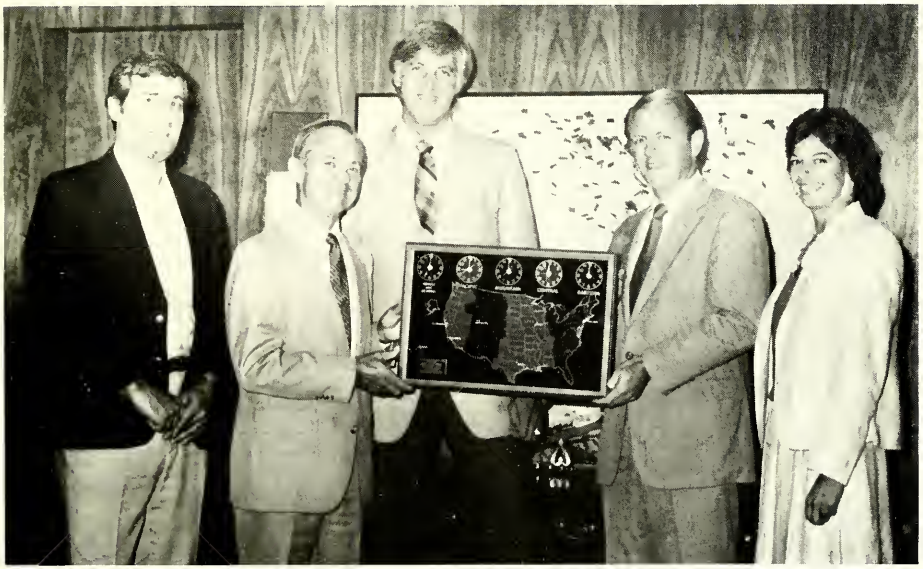
Virginia Steele
Corresponding Secretary

Northeastern Carolina Pharmaceutical Society — 1985–1986 Officers of the Society, installed at the annual Christmas meeting by Al Mebane, Executive Director of the North Carolina Pharmaceutical Association are:

Bill Brown, Greenville, President
Dean Bryan, Tarboro, Vice President
Mike Adams, Ahoskie, Secretary Treasurer

Priscilla C. Brown was elected vice-chair of the Board of Pharmaceutical Specialties at its recent meeting in Washington, D.C. Pharmacist Brown is a consultant specializing in skilled and intermediate nursing home pharmacy services.

The BPS was created by APhA in 1976 to grant recognition of appropriate pharmacy practice specialties, to establish standards for certification and recertification of pharmacists, to grant certification and recertification, and to serve as a coordinating agency and informational clearinghouse for organizations and pharmacists in recognized pharmacy practice specialties.



North Carolina Mutual Wholesale Drug Company, Durham, N.C., was selected to receive Syntex Laboratories' 1985 Regional Wholesaler of the Year Award for the Mason-Dixon region. The award acknowledges the vital role of the wholesaler and honors outstanding wholesalers in each region for their exceptional performance and spirit of cooperation with Syntex field personnel. John Bivens (left), North Carolina Mutual Wholesale Drug buyer, and Ralph Rogers (second from left), North Carolina Mutual Wholesale Drug executive vice president, receive the award from Roger Kinsey (center), Syntex district manager, Robert Hoerdeman (second from right), Syntex regional director, and Judy Smith, Syntex professional medical representative.

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CORRESPONDENCE COURSE

ADVISING CONSUMERS ON OTC PRODUCTS FOR RELIEF OF ORAL DISCOMFORT

by J. Richard Wuest, R.Ph., Pharm.D.
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and
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Professor of Pharmacology and Toxicology
Ohio Northern University, Ada, OH

GOALS

The goals of this lesson are to:

1. define terms relating to oral health care;
2. describe the treatment of minor mouth disorders with OTC agents.

OBJECTIVES

At the completion of this lesson, the successful participant will be able to:

1. recognize safe and effective OTC agents for treating minor mouth disorders;
2. identify the pharmacologic action of OTC oral and dental products;
3. explain the proper technique for applying these products;
4. know when to refer the patient to a dentist or physician.

GLOSSARY OF ORAL HEALTH CARE TERMS

1. **Abrasion:** the wearing away of tooth substance through some mechanical process; usually occurs on the exposed root surfaces of teeth, but may be seen elsewhere.
2. **Abrasive:** a solid material which cleans or polishes. Abrasives are important inactive ingredients in anticaries dentifrice formulations, and typically comprise up to 50 percent of the total formulation. Abrasives are added to dentifrices to facilitate mechanical removal of dental plaque, debris, and stain from tooth surfaces.
3. **Anesthetic:** a drug which causes reversible loss of feeling or sensation. *General anesthetics* are given by inhalation or intravenous injection, and they cause a loss of consciousness as well as a loss of sensation. *Local anesthetics* are applied directly to the nerve tissue in which they block sensory receptors and passage of nerve impulses centrally.
4. **Anticaries Agent:** an agent which aids in the prevention of dental caries (decay or cavities).
5. **Antimicrobial Agent:** an agent that kills microorganisms, or prevents or inhibits their growth and reproduction, and contributes to claimed effects of the product in which it is included. An *antimicrobial preservative* is an agent that kills organisms, or prevents or inhibits their growth and reproduction. It is included in a product formulation only at a concentration sufficient to prevent spoilage or prevent growth of inadvertently added microorganisms, but does not contribute to the claimed effects of the product to which it is added.
6. **Antiseptic:** an agent that contains chemicals intended to kill or temporarily prevent multiplication of harmful germs which may be present on the skin or oral mucous membranes.
7. **Astringent:** an agent that causes contraction of the tissues or arrest of secretions by coagulation of proteins on a cell surface.

in the service of pharmacy

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8. **Cementum:** the bonelike material covering the root of the tooth. Cementum contains 45 to 50 percent organic, and the balance, inorganic matter. It contains many fibers which attach the tooth to the bone.
9. **Counterirritant Drug:** an irritating drug that is applied locally to the skin or oral mucosa for relief of pain originating from a structure other than the site of application. For example, a counterirritant drug might be applied in a dental poultice to the oral mucosa surrounding a tooth with a painful pulp.
10. **Debriding Agent:** an agent which causes the removal of foreign material or devitalized or contaminated tissue from or adjacent to a traumatic or infected lesion to expose surrounding healthy tissue.
11. **Decongestant:** an agent that reduces congestion or swelling. In OTC use for mucous membranes, the term generally refers to sympathomimetic drugs that act by vasoconstriction.
12. **Demulcent:** a bland, inert agent that soothes and relieves irritation of inflammed or abraded surfaces such as mucous membranes.
13. **Dental Calculus:** mineralized dental plaque that accumulates on the tooth surface principally at the gum margin. One of the major fates of plaque is mineralization. Plaque serves as a matrix for calculus formation. The surface of calculus is usually covered with a nonmineralized layer of plaque.
14. **Dental Fluorosis:** a mottling (discoloration) of tooth enamel resulting from imperfect mineralization associated with excessive ingestion of fluoride. Brown or black stains develop because the poorly calcified surface absorbs colored materials. The frequency and extent of dental fluorosis is chiefly related to the fluoride content of drinking water.
15. **Dental Gel:** a dosage form for delivering an anticaries agent to aid in the prevention of tooth decay; formulated in an anhydrous glycerin base with suitable thickening agents included to adjust viscosity.

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16. **Dental (Dentin) Hypersensitivity:** a term which implies that the teeth are much more reactive than normal to sensory stimuli such as heat, cold, sour, sweet, or touch. Hypersensitivity can occur when dentin is exposed to the oral environment as a result of gum recession, abrasion, erosion, or a defect in the enamel or cementum.

17. **Dental Plaque:** a gel-like mat firmly attached to the surface of a tooth or restoration, but removable from exposed areas by thorough mechanical cleansing; the gel-like mat is made up of the following:
    a. **Microbial Masses.** Microorganisms are the dominant components of mature plaque. The microbial composition of plaque is complex, but in general, an initial predominance of gram-positive organisms eventually shifts to gram-negative, along with a shift of aerobes to anaerobes.
    b. **Intermicrobial Matrix.** This is a polysaccharide-protein complex derived from bacteria and saliva, and in areas adjacent to the gingival tissues, from gingival fluid. Of the polysaccharides, dextran and levan are the most significant; both are extracellular polysaccharides produced by bacteria. Dextran is the more significant because of its greater quantity and relative insolubility; levan is a much smaller component of the matrix and is used as a carbohydrate nutrient by plaque bacteria in the absence of exogenous sources.
    c. **Nonbacterial Cellular Inclusions.** Both the epithelial cells derived from the tissue in the crevices between teeth and the leukocytes migrating across that area contribute to plaque formation and structure.

18. **Dental Rinse:** a term used to designate a liquid dosage form for rinsing between and around the teeth.

19. **Dental Tubules:** microscopic channels in the dentin which contain: (a) the odontoblastic process (projection of the dentin-producing cells which line the pulp chamber and produce dentin); (b) tissue fluid bathing the process; and (c) varying degrees of mineral. While it is controversial whether these tubules contain nerves, there is general agreement that the tubules contain the means for transmitting pain perception.

20. **Dentifrice:** a substance used with a toothbrush to clean the accessible surfaces of the teeth. Dentifrices are ordinarily composed of water, detergent, humectant, binder, flavoring agent, and finely powdered abrasive as the principal ingredients.

21. **Dentin:** the calcified tissue forming the bulk of the tooth. It is composed of approximately 70 percent inorganic material, 18 percent organic material, and 12 percent water. Dentin is covered by the enamel of the tooth crown and the cementum of the root. It encloses the soft pupal tissues of the tooth. Dentin is a tubular structure, and processes from cells in the pulp (odontoblasts) penetrate the dentinal tubules. There are three types of dentin: see primary dentin, secondary dentin, and tertiary dentin.

22. **Dentin Densensitizer:** a drug which acts on the dentin to block perception of stimuli perceived by patients with dental hypersensitivity. This term is synonymous with tooth desensitizer.

23. **Dental Poultice:** a topical dosage form which is confined within a porous sac and is applied to the oral mucous membrane in order to supply medication in the presence of heat and moisture.

24. **Detergent:** surface-active ingredients which facilitate the removal of foreign matter from solid surfaces when they are washed.

25. **Enamel:** the compact and hard substance that covers the crown of the tooth and provides protection for the dentin. The inorganic content of mature enamel is 96–97 percent, the remainder consisting of organic matter and water.

26. **Fluoride:** the negatively-charged atom of the chemical element fluorine. The deposition of fluoride in dental enamel has been shown to increase resistance to enamel solubility and, therefore, dental decay.

27. **Gargle:** a fluid, which may be flavored, medicated, or both, used to rinse or bathe the posterior part of the oral cavity, with the additional intent to expel mucus from the throat.

28. **Germicide:** an agent that destroys microorganisms. The term includes bactericide, fungicide, virucide, and amebicide.

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29. **Gingivitis:** inflammation occurring in the gums as a response to bacterial plaque.
30. **Iodophor:** there are at least three categories of iodophors: (1) hydroalcoholic solutions of elemental iodine and iodides; (2) elemental iodine complexed with various surfactant compounds; and (3) elemental iodine complexed with various nonsurfactant compounds such as PVP-iodine complex (povidone-iodine).
31. **Mouth Odor:** a general term for an odor emanating from the oral cavity. It may or may not be offensive. When such odor is perceived as unpleasant, obnoxious, offensive, or objectionable, terms such as *malodor, halitosis,* or *bad breath* may be used.
32. **Mouth (Oral) Rinse:** a solution, often containing breath-sweetening, astringent, demulcent, detergent, or germicidal agents, which is used for refreshing and cleansing the mouth, or for gargling. In some instances, such a vehicle may be used to deliver an active drug to the oral mucosa or teeth. A *dental rinse* is a liquid used to rinse between and around the teeth.
33. **Necrosis:** refers to circumscribed localized areas of cell or tissue death caused by almost any type of severe injury.
34. **Oral Mucosal Analgesic:** an ingredient used in dental care drug products for topical application in the oral cavity to provide temporary relief of oral discomfort by an anesthetic or analgesic effect.
35. **Oral Mucosal Injury Agent:** an agent which relieves oral soft tissue injury, by cleansing or promoting the healing of oral wounds (minor oral irritations).
36. **Oral Mucosal Protectant:** an agent which is a pharmacologically inert substance that forms an adherent, continuous, flexible, or semirigid coating when applied to the oral mucous membranes. This coating protects the area from further irritation due to the activity of oral structures.
37. **Pellicle:** a product of saliva which is bacteria-free and contains glycoproteins, derivatives of glycoproteins, polypeptides, and lipids. A cleaned tooth surface will form a pellicle within minutes. The formation of this structure is believed to be the first step in plaque formation, although not always a necessary prerequisite.
38. **Pharynx (Throat):** the musculomembranous sac between the mouth and nostrils and the esophagus. It is continuous below with the esophagus; above it connects with the mouth, nasal passages, and auditory (Eustachian) tubes. It is subdivided into the following parts:
    (a) **Nasopharynx:** the part above the level of the soft palate.
    (b) **Oropharynx:** the part that lies between the soft palate and the upper edge of the epiglottis.
    (c) **Laryngopharynx:** the part that lies between the upper edge of the epiglottis and opens into the larynx and esophagus (sometimes called hypopharynx).
39. **Plaque:** a patch on the surface of the oral mucosa or tooth made up of a mass of microorganisms. Depending on bacterial activity and environmental factors, it can give rise to caries (cavities), calculus, or inflammatory changes in the mucosal surface or tooth.
40. **Primary Dentin:** the well-structured dentin that is deposited during the original formation of the tooth. Dentin deposited later in life differs in structure and can be distinguished from primary dentin microscopically by a demarcation line that stains darkly.
41. **Secondary Dentin:** dentin formed after the original primary dentin of the tooth has been deposited. It forms on the inner, or pulpal surface of the primary dentin as a physiologic process or as a pathologic response to thermal, mechanical, or chemical irritants. Secondary dentin is not as well-structured as primary dentin and can be distinguished microscopically by its irregular morphologic pattern.
42. **Sloughing:** a slough is a mass of dead tissue in, or cast out from, living tissue. Sloughing is the formation or separation of dead from living tissue.
43. **Tertiary Dentin:** designates dentin formed as a result of more severe injuries or insults to the tooth, such as dental caries, marked abrasion, or extensive erosion. Tertiary dentin is of very poor structure and is limited to the area of irritation.
44. **Toothache Remedy:** an agent used for the temporary relief of pain arising as a result of an open tooth cavity.
45. **Topical Analgesic:** a substance applied to an epithelial surface (e.g., skin or mucous

membrane) that relieves pain without necessarily abolishing other sensations; or one that causes partial blockade of subcutaneous or submucosal terminal nerve endings so that a minimal stimulus evokes no painful response, but a greater stimulus does.

ADVISING CONSUMERS ON OTC PRODUCTS FOR RELIEF OF ORAL DISCOMFORT

This lesson will review important aspects of oral and dental care, and the OTC drugs appropriate for self-use in preventing or treating oral diseases and injuries. To assure that the reader understands the common terminology used throughout this lesson, attention is directed to the Glossary of Oral Health Care Terms. This terminology was derived from the "official" definitions that were adopted by various FDA advisory panels which reviewed oral health care drugs. It is recommended that participants save this glossary for future reference.

OTC AGENTS USED TO RELIEVE ORAL DISCOMFORT

These agents fall into five broad categories: 1) oral discomfort remedies, i.e., oral mucosal analgesics; 2) oral mucosal protectants; 3) tooth desensitizers; 4) toothache remedies; and 5) products for oral health care, i.e., analgesic/anesthetics, antimicrobials, astringents, debriding agents, decongestants, demulcents, and expectorants. Three of the four categories of agents that are reviewed in this lesson (i.e., mucosal analgesics, mucosal protectants and toothache remedies) contain at least one ingredient that was ruled to be safe and effective for continued OTC marketing. More ingredients should follow in the future. The fourth group, tooth desensitizers, contains several agents that were almost approved. The status of ingredients in each of these categories is contained in Table 1. Each ingredient will be discussed in this lesson..

TABLE 1
FDA Advisory Panel Rulings on Active Ingredients in OTC Drug Products for Relief of Oral Discomfort

A)	**Mucosal Analgesics**	
	Category I	Benzocaine (5–20%)
		Butacaine (4%)
		Phenol (0.25–1.5%)
		Sodium phenolate (0.25–1.5%)
	Category II	Camphor
		Methyl salicylate
	Category III	Benzyl alcohol
		Cresol
		Thymol
B)	**Mucosal Protectants**	
	Category I	Benzoin (10–20%)
	Category II	None
	Category III	Myrrh
C)	**Tooth Densitizers**	
	Category I	None
	Category II	Sodium fluoride, strontium choloride, and EDTA (combined)
	Category III	Citric acid/sodium citrate in poloxamer 407
		Fluoride salts
		Formaldehyde
		Potassium nitrite
		Strontium chloride
D)	**Toothache Remedies**	
	Category I	Eugenol (85–87%)
	Category II	Capsicum
		Menthol
		Methyl salicylate
	Category III	Benzocaine
		Benzyl alcohol
		Butacaine
		Creosote
		Cresol
		Eugenol (1–84%)
		Phenol
		Thymol

*Category I - safe and effective
Category II - proposed to be banned from future sale
Category III - needs more study before final ruling can be made

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ORAL MUCOSAL ANALGESIC/ ANESTHETICS

The oral mucosal analgesics are intended for short-term use to provide relief of pain, until the lesion heals, or until more definitive treatment can be initiated by a dentist or physician. Those agents most commonly used are benzocaine, butacaine, aromatic alcohols (i.e., eugenol), and phenol and its derivatives.

Benzocaine has been the most widely used anesthetic agent because it is effective in low dosage. Even in high concentrations, serious toxicity problems are unlikely. It is also nonirritating to tissue unless the individual is allergic to it. Benzocaine has an almost immediate onset of action. This can be lengthened somewhat by incorporating it in a vehicle such as Orabase®, which remains in contact with the oral mucosa. It is reported that the pain-relieving action of benzocaine is localized to the site of application. Whatever drug is absorbed is insufficient to provide analgesia or anesthesia (and therefore side effects) elsewhere in the body. Benzocaine, as well as the other local anesthetics, appears to act by interfering with the movement of sodium into or out of nerve fibers, and, therefore, interrupts the passage of pain impulses through the affected area to the brain.

It has been used widely since the turn of the century with no significant reports of toxicity. However, drug-induced methemoglobinemia may occur in infants following high doses of benzocaine suppositories. Thus, the use of benzocaine-containing products in infants under six months is not recommended.

Butacaine is as effective as benzocaine, but reportedly more toxic. It, too, has a long history of safe use. However, since it has a potential for causing toxicity reactions in high dosages, FDA limited its availability to 0.75 to 4% concentrations. The FDA advisory panel reporting on oral discomfort agents has suggested that butacaine be available in single use units, with no more than six units per package. It also recommended that a

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warning to consumers appear on the label advising them not to use more than one unit at a time, no more frequently than one every three hours, and not to exceed three doses daily. Additionally, the label should warn against use for teething pain in infants.

Phenol and **sodium phenolate** (0.25 to 1.5%), in a hydroalcoholic solution containing up to 20% alcohol, is an effective dental rinse. Phenol and sodium phenolate, with alcohol in concentrations up to 70% for direct application, are effective oral mucosal analgesics. Higher strengths are too irritating, and possibly corrosive.

Benzyl alcohol, cresol, and **thymol** have some, but insufficient, evidence of effectiveness on the oral mucosa. They have demonstrated local anesthetic activity on skin, but controlled studies on their safety and effectiveness when applied to the oral mucosa are needed.

Camphor and **methyl salicylate** have been ruled "unsafe" as oral mucosal analgesics. The concern for accidental ingestion of camphor is too great, in the opinion of the FDA advisory panel. (Camphorated oil was removed from the OTC market just prior to this panel submitting its report.) Methyl salicylate, also frequently included in analgesic balms for application to the skin, is too irritating for application to oral mucosa. Both of these agents may be included in low concentrations for their flavoring properties.

ORAL MUCOSAL PROTECTANTS

Oral mucosal protectants are defined as adherent, flexible, insoluble, pharmacologically inert substances which form a continuous, semirigid coating that protects the area from further irritation by chewing, swallowing, etc. They can provide temporary relief of discomfort from minor thermal and chemical burns, irritations, traumatic ulcerations or canker sores.

Benzoin preparations (the tincture and the compound tincture) have demonstrated sufficient proof of safety and effectiveness to be placed in Category I. In the treatment of oral lesions, the area should be dry (benzoin is not water soluble) before applying the product. This provides a transient protective coating. Neither product should be diluted because this reduces its effectiveness as a protectant. It should not be applied more often than every two hours. The advisory panel suggested that it be packaged in 30 ml sizes or less, and that they have child resistant caps.

Although tincture and fluidextract of **myrrh** have been applied to oral tissue for the same use for many years, the panel could not find documented evidence of effectiveness. Therefore, such studies will be required before it can be officially considered for this indication.

OTC TOOTH DESENSITIZERS

Tooth (dentin) desensitizers are indicated for treating ultrasensitive teeth. Dentin, the calcified tissue that composes the bulk of the tooth, contains the tooth's sensory apparatus. Normally, dentin is protected by enamel on the crown of the tooth and cementum at the root. When these two highly calcified structures are lost due to erosion, abrasion, cavities, chipping, or other causes, the exposed dentin can become sensitive to various stimuli including chemicals, heat, cold or touch. Agents that are claimed to provide tooth desensitization include fluoride salts, strontium chloride, potassium nitrate, and formaldehyde.

The panel could not formally rule on agents used as tooth desensitizers for several reasons. Consumers cannot self-diagnose dental hypersensitivity or its cause, because the exact mechanism of action of dental hypersensitivity is not yet known. Also, the means of evaluating desensitizing agents is more subjective than objective.

However, the advisory panel suggested that the items mentioned above are useful in providing temporary relief until professional help can be obtained. Also, they are appropriate for use after the condition has been correctely diagnosed and repair work has been made. The panel left the door open for continued OTC availability of tooth desensitizers by placing them in the "needs more study" category. They are all safe for OTC marketing, but of questionable efficacy for self-use. Manufacturers of products containing them must now prove this effectiveness.

American Pharmaceutical Association
133rd Annual Meeting
March 16-20, 1986

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Give the Answers!

By anticipating your patients' questions on drugs and answering them even before they are asked, you can assert, all the more strongly, the pharmacist's appropriate role in patient drug education and community health.

The National Council on Patient Information and Education (NCPIE) campaign, "I Give the Answers," is now in full swing. They are asking you to assert your traditional leadership and to demonstrate your personal commitment in this vital area by answering your patients' question as you always do, and by providing answers even when your patients don't, but should ask questions on their medicines, so that they are taken safely and effectively.

NCPIE strongly recommends that every patient know:

1. The name of the medicine and what it is supposed to do.
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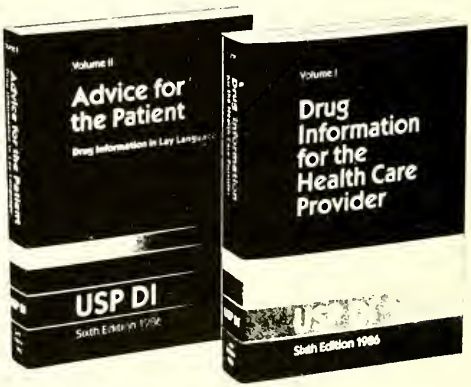

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OTC TOOTHACHE REMEDIES

Toothache remedies provide temporary relief of pain caused by an open tooth cavity. There are two types — those applied to the open cavity and those applied to the adjacent gum via a poultice. These agents are controversial. Some representatives of the dental profession have expressed concern that their effectiveness is doubtful. However, the FDA advisory panel feels that safe and effective toothache remedies have a place in the OTC market, so that consumers have medication available until professional help can be obtained.

When dental pulp is exposed to irritation, intense pain and inflammation can result. This inflammation may be *reversible,* which is correctable, and *irreversible,* which renders the tooth nonviable. Dehydration of dentin is one factor which contributes to the formation of irreversible inflammation. Since this can be caused by medications containing alcohol (20% and above), they are contraindicated for use as toothache remedies.

It is also considered irrational to place an occlusive substance, such as wax, gum, paraffin or cotton (with or without medication) into the tooth cavity. This may result in intensified pain and spread of infective organisms into the deeper areas of the tooth, socket or general circulation.

Even though substances such as beeswax, paraffin and sandarac (an alcohol soluble, water insoluble resin) that are applied to cotton pellets have been used in open dental cavities for years, FDA believes that the risks associated with occlusion do not warrant continued OTC availability of these items. Sandarac solutions in alcohol are especially dangerous since the high levels of alcohol could dehydrate the dentin and destroy the tooth. Only dentists can apply this product safely.

The panel that reviewed these agents also expressed concern about poultice dosage forms because they cause further irritation to the damaged mucosa. Additionally, they could be erroneously instilled into dental cavities, and might be accidentally swallowed resulting in systemic effects. While there is insufficient scientific evidence that counterirritants contained in poultices actually relieve toothache, numerous empirical observations and testimonials suggest that these agents are useful. Supposedly, by irritating the oral mucosa around the aching tooth, the sufferer's perception of deep-seated dental pain is alleviated. Since both types of pain may travel along the same neurons, the possibility exists that poultices work. Additionally, the placebo effect of placing a poultice near a sore tooth is very real. The panel concluded that, with proper warnings to prevent misuse, dental poultices should remain available OTC, provided that their manufacturers prove the active ingredients are safe and effective.

Of the dozen or so substances reviewed by the FDA advisory panel, only **eugenol (clove oil)** in an 85 to 87% concentration has sufficient documented proof of safety and effectiveness with proper labeling. There is a potential safety problem because eugenol is sufficiently irritating to damaged viable pulp. Eugenol should not be used for pain due to reversible pulp damage which is characterized by intermittent pain of varying intensity. Eugenol should be used only for pain caused by already irreversibly damaged pulp, i.e., that resulting in persistent, throbbing pain. Eugenol acts by a local anesthetic action on the nerve fibers.

Eugenol concentrations less than 85% were placed in the "needs more study" category since there are insufficient data to prove effectiveness. Benzocaine and butacaine were also placed in this category. Even though they have been proved effective as oral mucosal analgesics, they have not been proved effective when instilled into a tooth cavity. Benzyl alcohol is also included in this group.

Phenolic compounds including cresol, creosote, thymol, and phenol itself have demonstrated anesthetic activity (they paralyze sensory nerves), counterirritant effects, and germicidal action when applied topically. However, they were placed in this category because none has yet been proven effective when applied inside a tooth cavity.

Safety is another important consideration. At full strength, the phenolic compounds are too corrosive and dangerous to use. However, at strengths of 0.25 to 1.5% for creosote, 0.25 to 1.0% for cresol, and up to 1.5% for phenol, all are safe and effective topical anesthetics when applied to unbroken skin or mucous membranes. Should their sponsors eventually be able to prove the same for application into tooth cavities, the substances will be approved for use as toothache remedies.

Thymol is included in many mouthwashes. Dentists use it mixed with phenol and camphor

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to prepare cavities before filling, and mixed with zinc oxide to form a protective cap for teeth. It has been used as an OTC toothache remedy, but definite proof of effectiveness has not yet been demonstrated.

Capsicum was assigned Category II status as a counterirritant to be applied to healthy oral mucosa. It is considered to be unsafe for application to damaged mucous membranes or directly into the cavity because it is too irritating. It can actually injure viable dental pulp.

Menthol and **methyl salicylate** were ruled to be unsafe for use as toothache remedies for the same reasons mentioned earlier. As with oral mucosal analgesics, they can be included in low concentrations for flavoring purposes. At strengths adequate to produce their local anesthetic effect, they are too irritating, and, therefore, unsafe.

CONSUMER ADVICE

Assuming that some or all of the drugs that require more studies are eventually proven to be safe and effective for the four indications reviewed, pharmacists can provide advice on their proper use. The published indications and warnings for each group are listed in Table 2.

Regarding the oral mucosal analgesics, benzocaine should be applied to the affected area three to four times a day, unless directed otherwise by a physician or dentist. There is no medically unsupervised recommended dosage for treatment of children under four years of age. Butacaine, if it is approved, will be available in unit dose containers (up to 30 mg.), indicated for a single treatment. It should be applied no more frequently than every three hours, and no more often than three times a day. It should not be used in children under twelve, except when advised by a physician or dentist.

Phenol-containing solutions, used as teething preparations, are recommended only for infants over four-months of age, and no more often than six times a day. When used as a dental rinse, the lower age limit is six years and the recommended schedule is up to six times a day.

As far as oral mucosal protectants are concerned, the individual should first dry the affected area with a cotton pledget or cotton tipped applicator. The pledget or applicator should be saturated with the protectant and applied approximately every two or three hours as needed. Tooth desensitizers are best applied with a toothbrush at least once a day, following normal brushing.

For toothache remedies, the individual should rinse the tooth to remove any food or debris from the cavity. A cotton pledget should be moistened with one to two drops of medication, placed in the cavity for approximately one minute, and removed. Adjacent areas should not be touched with the product. This procedure can be repeated up to four times a day.

CE TEST ON

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TABLE 2
Proposed Label Statements and Warnings for OTC Drug Products for Relief of Oral Discomfort

A) **Mucosal Analgesics**

1. Indications for the temporary relief of:
   pain due to minor irritation or injury of soft tissue of the mouth; dental procedures, dentures or orthodontic appliances, recurring canker sores when the condition has been previously diagnosed by a dentist, or sore gums due to teething in infants and children 4 months of age and older.

2. Warnings:
   - Do not use longer than 7 days.
   - If irritation persists, inflammation develops, or if fever and infection develop, discontinue use and see your dentist of physician promptly.
   - Do not swallow.
   - Do not exceed recommended dosage.
   - Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

- For products containing butacaine sulfate:
  a) Do not use in children under 12 years of age unless recommended by a dentist or physician.
  b) Do not use more than one unit at a time.
  c) Do not repeat more often than every 3 hours.
  d) Do not exceed 3 doses daily.
- For products indicated as teething remedies: "Fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, consult your physician."

B) **Mucosal Protectants**

1. Indications:
   - Forms a coating over the wound.
   - Protects against further irritation.
   - For temporary use to protect wounds caused by minor irritations or injury.
   - For protecting recurring canker sores when the condition has been previously diagnosed by the dentist.
2. Warnings:
   - Do not use longer than 7 days.
   - If irritation persists, inflammation develops, or if fever and infection develop, discontinue use and see your dentist or physician promptly.
   - Do not swallow.
   - Do not exceed recommended dosage.
   - Use in children under 12 years of age should be supervised.

C) **Tooth Desensitizers**

1. Indications:
   - "To aid in the reduction of painful sensitivity of the teeth to cold, heat, acids, sweets or contact."
2. Warnings:
   - Do not continue use after 2 weeks except under supervision of a dentist.
   - Do not swallow.
   - Use in children under 12 years of age should be supervised.
   - Sensitive teeth may indicate a serious problem which needs prompt care by a dentist.
   - See your dentist as soon as possible whether or not relief is obtained.
   - If irritation persists, inflammation develops, or if fever and infection develop, discontinue use and see your dentist or physician promptly.
   - Do not exceed recommended dosage.

D) **Toothache Remedies**

1. Indications:
   - "For relief of throbbing, persistent toothache due to a cavity, until a dentist can be seen."
2. Warnings:
   - Use only in teeth with persistent, throbbing pain.
   - Do not use longer than 7 days.
   - If irritation persists, inflammation develops, or if fever and infection develop, discontinue use and see your dentist or physician promptly.
   - Do not swallow.
   - Do not exceed recommended dosage.
   - Use of this product in children under 12 years of age should be supervised.
   - A dentist must be seen as soon as possible whether or not the pain is relieved.
   - Toothaches and open cavities indicate serious problems which need prompt attention by a dentist.

PLASTIC PRESCRIPTION BOTTLES FOR ORAL LIQUIDS

USP has received a number of inquiries from pharmacists regarding the safety, legality, and suitability of utilizing the empty plastic bottles being marketed for dispensing liquid preparations pursuant to prescription. Please be advised that USP has no information from any manufacturer concerning the chemical characteristics of its containers, and is not aware of the results of any stability testing of particular drug products in these containers.

In view of the fact that there are many formulations of pharmaceuticals on the market with different solvents and concentrations which might theoretically extract plasticizers, etc., from the plastic, or conversely, show a loss of potency, color, flavor, etc., through sorption by some types of plastic, USP cannot recommend use of these containers by dispensers until additional information is known.

We caution pharmacists utilizing these containers as substitutes for glass to carefully consider the characteristics of the products they are dispensing.

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CORRESPONDENCE COURSE QUIZ

Oral Discomfort

1. Which of the following has been found to be safe and effective for OTC sale as an oral mucosal analgesic?
   a. Benzyl alcohol
   b. Methyl salicylate
   c. Sodium phenolate
   d. Thymol iodide

2. All of the following OTC products have label warnings advising not to use them longer than seven (7) days *EXCEPT:*
   a. mucosal analgesics.
   b. mucosal protectants.
   c. tooth densensitizers.
   d. toothache remedies.
3. Which of the following is a synonym for oil of cloves?
   a. Eugenol
   b. Methyl salicylate
   c. Sandarac
   d. Thymol iodide

4. Because of the chance of dehydration leading to irreversible inflammation, alcohol is contraindicated for use in OTC toothache remedies in concentrations greater than:
   a. 20%.
   b. 50%.
   c. 70%.
   d. 95%.
5. Which of the following is considered by the FDA advisory panel to be a safe and effective OTC toothache remedy?
   a. Benzoin
   b. Eugenol
   c. Sandarac
   d. Yellow wax

6. The above agent (correct answer to #5) is also considered by the panel to be safe for use in treating pain caused by:
   a. irreversible pulp damage.
   b. reversible pulp damage.
7. Self-treatable pulp damage is characterized by:
   a. intermittent pain of varying intensity.
   b. persistent, throbbing pain.
8. All of the following statements about benzocaine are true *EXCEPT:*
   a. its action is localized with very little absorption to cause systemic effects.
   b. it appears to act by interfering with the movement of sodium into/out of nerve fibers.
   c. it has a slow onset and long duration of action.
   d. it interrupts the passage of pain impulses to the brain through the area to which it is applied.
9. To meet the definition of an OTC oral mucosal protectant, the drug must be:
   a. a local anesthetic.
   b. inflexible.
   c. non-adherent.
   d. pharmacologically inert.
10. The FDA advisory panel concluded that which of the following is a safe and effective oral mucosal protectant?
    a. Benzoin
    b. Camphor
    c. Eugenol
    d. Phenol
11. The calcified tissue that comprises the bulk of a tooth and contains its sensory apparatus is the:
    a. cementum.
    b. dentin.
    c. enamel.
    d. pellicle.
12. The local anesthetic that the FDA advisory panel recommended be commercially available only in single use units with no more than six units per package is:
    a. benzocaine.
    b. butacaine.
    c. clove oil.
    d. sodium phenolate.
13. Due to the chance of irritation and possible corrosive action, hydroalcoholic solutions of phenol for direct application are limited to no greater than which of the following concentrations of alcohol?
    a. 20%
    b. 50%
    c. 70%
    d. 95%

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14. The FDA advisory panel concluded that OTC tooth desensitizers are:
    a. both safe and effective.
    b. effective but of questionable safety.
    c. neither safe nor effective.
    d. safe but of questionable effectiveness.
15. The panel further concluded that placing OTC occlusive substances such as paraffin wax or cotton into a tooth cavity is:
    a. irrational.
    b. rational.

DR. T.C. SMITH CHANGES

The Board of Directors of Dr. T.C. Smith Company, Inc. is pleased to announce the following changes in Management as of September 1, 1985.

Frank S. Smith has been appointed Chairman and Chief Executive Officer.

Canie B. Smith has been appointed President and Chief Operating Officer.

Richard E. Hoffman has been appointed Division Manager of Dr. T.C. Smith Co., Asheville

Also effective September 1st:

Franklin H. Turner, Vice President, Systems & Development will assume the responsibility for Corporate Inventory management.

V. Roger Headrick will join the Firm as Corporate Sales Manager (Drug Divisions).

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3. a b c d	*6. a b c d*	*9. a b c d*	*12. a b c d*	*15. a b c d*

Evaluation ☐ Excellent ☐ Good ☐ Fair ☐ Poor

How long did it take you to read the article and compelete the exam?____

WEDDINGS & DEATHS

Donna Stephenson Griffin and NEAL FRANKLIN FOWLER, both of Goldsboro were married Saturday, September 21, 1985 at First Christian Church.

The bride, a graduate of Meredith College and Ohio State University is an organist and director of music at First Presbyterian Church in Goldsboro. The bridegroom, a graduate of the University of North Carolina at Chapel Hill School of Pharmacy, is chief pharmacist and assistant manager at Kerr Drugs in Goldsboro. They will live in Goldsboro.

Rebecca Colleen Garrison and GARY ELLWOOD TIFFANY, both of Raleigh were married Saturday, September 21, 1985 in Aversboro Road Baptist Church.

The bride is a graduate of East Carolina University. The bridegroom is a pharmacist at Rite Aid, and is a graduate of the University of North Carolina at Chapel Hill School of Pharmacy. They live in Lumberton.

MICHELLE DAWN TOUSIGNANT and Joseph Kevin Mack both of Mooresville were married in a 7 p.m. candlelight ceremony Saturday, October 19, 1985 at Mooresville Associate Reformed Presbyterian Church.

The bride attended Duke University and graduated from the University of North Carolina at Chapel Hill School of Pharmacy. She is a pharmacist at Lowrance Hospital. The bridegroom graduated from North Carolina State University with a B.S. in industrial engineering. He is employed by Allegheny International Exercise Co. in Lincolnton. They make their home in Mooresville.

JAMES M. SMITH, JR., 59, the Chairman and Chief Executive Officer of the JM Smith Corporation passed away December 27, 1985. Smith was known as an innovator in computer software operating systems. The research he did in 1976 was the beginning of the operating system that is being used by the QS/1 Pharmacy System in over 1,300 pharmacies in the United States and in Canada.

In 1951, he took over Smith Drug Company, a wholesale pharmaceutical supply company, which was founded by his father, that now serves retail and hospital pharmacies in three states.

A native of Asheville, Smith was the son of Ethel Rickbeil Smith of Clinton and the late James Matthew.Smith Sr. He was a graduate of Massachusetts Institute of Technology and the University of South Carolina School of Pharmacy.

Memorials may be made to Mobile Meals, P.O. Box 461, Spartanburg, S.C. 29304.

SAM JENKINS, Walstonburg, died October 27, 1985 at the age of 84. Born in Fairmont, Jenkins was a 1926 graduate of the UNC of Pharmacy and was licensed in North Carolina in 1928. He served as mayor of his home town, sunday school superintendent for 25 years, and was active in other community organizations. He served on many of the NCPhA committees and was a candidate for NCPhA president in 1954. He was featured in an article by News & Observer columnist Dennis Rogers in May 1977 in that paper.

TOM R. ROBINSON, Jr., Goldsboro, died November 9, 1985. He was 77 years old. Robinson served Goldsboro as alderman, mayor pro tem and was elected mayor in 1964. He held that post for 5 years. He was a member of the Elks Lodge, Masonic Temple, Goldsboro York Rite, the Sudan Temple of New Bern and St. Paul's United Methodist Church. He closed his pharmacy, Robinson's Drug Store, in 1975, after almost 100 years of family operation.

HERMAN O. THOMPSON, Chapel Hill, died Wednesday November 5, 1985 at Hillcrest Convalescent Center. A native of Indiana, Thompson was professor of pharmacy at the UNC School of Pharmacy in Chapel Hill from 1946 until his retirement in 1977. Thompson received his B.S. in Pharmacy from UNC, and his Masters and Ph.D. from Purdue University. His professional career included teaching at Purdue, University of Georgia and University of Illinois, serving as an Eli Lilly Research Fellow and sales representative, and as a practicing pharmacist.

MATTHEW C. SAVAGE, Roanoke Rapids, died November 18, 1985 at the age of 80. He was licensed by examination in 1940 and operated a pharmacy in Roanoke Rapids for many years prior to his retirement in 1982. A native of Spring Hope, Savage worked in Wilson and Rocky Mount before going to Roanoke Rapids. He was active in the Rotary Club, and was a member of the Rosemary Baptist Church. His son Bill is also a pharmacist.

STROTHER APPOINTMENTS

Ronald E. Carey, President of Strother Drug Company, has announced several appointments. J. Larry Salmon has been named Vice President and Division Manager of the Justice Drug (Greensboro) Division. David R. Wright has been appointed Vice President and Controller and James H. Carey has been appointed Merchandise Manager.

Mr. Salmon joined the Justice Drug Company in 1963, working in many areas of the Company, the most recent being Division Manager since 1983. He will continue to manage the Greensboro distribution center. Mr. Salmon is a native North Carolinian and currently resides in Liberty, North Carolina.

Mr. Wright holds a BS degree in Accounting from Virginia Polytechnic Institute and State University and is a certified public accountant. He was employed by Strother in 1974 as corporate controller. Previously, he was employed by Dalton, Pennell & Co., CPA's. Mr. Wright will continue to have the overall financial responsibility for all four Strother distribution centers. Mr. Wright is a Lynchburg, Virginia native and a lifetime resident of the area.

Mr. Carey is a 33 year employee of Strother. He has worked in many areas of the Company, the most recent as a buyer in the Lynchburg distribution center. Mr. Carey will now have the corporate responsbilities as merchandise manager. He is also a Lynchburg native and a lifetime resident of the area.

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The Department will be relocating into a new facility by the end of 1985 and is beginning program planning for improved admixture services and complete departmental computerization. We seek energetic and motivated practitioners to grow with us for the future. Persons interested should contact the Human Resources Department, St. Joseph's Hospital, 428 Biltmore Ave., Asheville, N.C."

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Available for relief work in the Triangle Area thru March. Call Toni Mascherin: (919) 929-4411.

Relief Pharmacist available for the Charlotte, and Gastonia areas of North Carolina. Recently relocated, former Pharmacy owner, prefers relief work. Phone Kern Stafford 803-548-0561.

STAFF PHARMACIST: North Carolina Baptist Hospital, a 701-bed facility affiliated with Bowman Gray School of Medicine, has opening in the Satellite Pharmacy. The pharmacy offers unit dose, nutrition support service, clinical services, and a drug information service. Winston-Salem is located in the Beautiful Piedmont section of North Carolina with beaches and mountains non more than an afternoon's drive. Winston-Salem's cultural attractions include presentations by the North Carolina School of the Arts, Piedmont Chamber Orchestra, Winston-Salem Symphony and NC Dance Theatre. For more information, send resume or call collect: Letha Huffman, NC Baptist Hospital, 300 S. Hawthorne Rd., Winston-Salem NC 27103.

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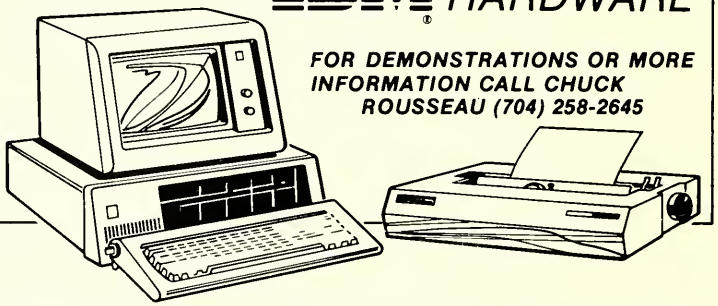

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FEBRUARY 1986 VOLUME 66 NUMBER 2

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HOUSEHOLD POISONINGS: A NATIONAL PROBLEM

Over 90 percent of all accidental poisonings occur in the home, and two-thirds of them involve children under the age of six. So says a study conducted by the American Association of Poison Control Centers (AAPCC).

The Study is the largest investigation ever of poisoning cases in the United States. It was developed and directed by the AAPCC's data collection committee.

"Sixty-four percent of the poisonings involved children," the AAPCC says. "Most childhood poisonings happen in the home in areas where common household products are stored or used. The best treatment for a poisoning is to prevent it from ever happening. Get the number of your poison center and call them for information or assistance."

Poisons are Everywhere

According to AAPCC, the number of poisonings is not surprising when you realize that the average home contains a multitude of things that can be deadly when swallowed. Some are obvious hazards: medicine, cleaning products, insecticides, lighter fluid, shoe dye, nail polish, and paint. Other potential poisons lurk in seemingly innocent forms, such as cigarette butts and certain plants.

Small children are at risk because they are, above all, explorers: obnoxious smells and unpleasant tastes seldom deter them from putting an unfamiliar substance in their mouths. Therefore, parents need to take an inventory of poisonous substances in the household and take measures to reduce the poisoning risk to all family members.

To reduce the risk of accidental poisoning, AAPCC suggests a family poison education program. They advise, "take a tour of the house and make a list of all substances that you think may be poisonous. Write down any questions you may have and contact your local poison control center for answers."

Important steps a parent can take include use of child-resistant packaging and appropriate storage and handling of dangerous products.

The Bathroom

The bathroom, where many potentially toxic substances are stored, is a good place to start.

Common items like medication, cleaning products, cosmetics and nail polish are all sources of danger if misused. The AAPCC study showed that medications accounted for the largest number of accidental poisonings.

However, most can be prevented by the following:

- Childproof the medicine cabinet with a reliable lock. Pill bottles should be clearly and accurately marked. Old medicines should be flushed down the toilet.
- Keep all potentially harmful products in child-resistant packages.
- Don't leave children alone with open bottles of medicines or household cleaners — even for a few seconds.
- Keep cosmetics and household cleaners tightly sealed and locked away. Cosmetics caused over 100,000 poisonings, more than 90,000 of which involved children under six.

The Bedroom

People often keep medications in the bedroom, where small children can get into them.

If you must keep medications in the bedroom, place them in a drawer that can be securely locked. Clothing bags containing moth balls should be kept in the attic, or in a locked closet. Keep cosmetics, shoe polish, and perfume locked away from small children as well.

The Kitchen

Predictably, aside from the bathroom, the kitchen may be the biggest trouble spot in the house. Many toxic substances, especially household cleaners, are kept there. Since the kitchen is often a family gathering spot, parents need to take extra precautions.

These include marking all poisons clearly with an indelible marking pen and storing them in a high cabinet that can be locked. Bleaches and disinfectants caused almost 20,000 poisonings.

Be especially careful around dinner time when most accidental poisonings in children occur, probably because parents are distracted and household activity generally increases.

Around the House

Many poisons are present in all areas of the house, and may be as dangerous as kitchen and bathroom products because they are not properly contained or stored, or even considered poisons.

Cleaning fluids, rags or mops left even temporarily in the living or family room can be tempting toys to a toddler. The same is true of oily rags, paints, varnishes and woodworking fluids likely to be found in the garage, basement or tool shed.

It's a good idea to thoroughly check each room in your house, and properly store each potentially dangerous substance. For items you're not sure about, make a list and take it to your local poison control center for advice. And consider the following:

- Keep your pocketbook, which may contain potentially toxic cosmetics and medications, out of the grasp of children.
- Eighty-three percent of all alcohol poisonings involved children under six. Keep the liquor cabinet locked at all times.
- Remember any plant may cause unexpected reactions in certain people. Keep plants out of a child's reach. Eating the leaves of toxic plants caused almost 200,000 poisonings.
- Keep fertilizers, gas cans and other toxic items found in the garage tightly sealed and out of harm's way. Insecticides and pesticides accounted for an estimated 75,000 poisonings.

What to do if a Poisoning Occurs

The AAPCC recommends the following:

- Call for immediate assistance. If the victim isn't breathing or is unconscious, begin mouth-to-mouth resuscitation.
- Display the phone number of your local poison control center near the phone. Stay calm — often the victim can be treated without leaving the home. Be ready to give complete details on the substance, how much was swallowed, and the victim's age, size and symptoms.
- Have a bottle of ipecac syrup to induce vomiting. Contact your poison control center, hospital emergency or physician before using.
- Never induce vomiting of corrosive substances such as drain cleaners, ammonia or blech.
- A corrosive substance in the eye is an emergency. Flush the eye with lukewarm water for 15 minutes. Then call your poison control center.
- Give immediate assistance to victims exposed to poisonous gases by getting them fresh air. Use mouth-to-mouth resuscitation if necessary.

Use your poison control center as a clearinghouse for information. Its telephone number is listed on the inside cover of your directory.

NEW FILM PRESENTATION FOCUSES ON CAREER DECISIONS FACED BY HIGH SCHOOLERS

The National Association of Chain Drug Stores, Inc. (NACDS) and Merrell Dow Pharmaceuticals Inc. today announced the release of "The Right Choice," a new film which is designed to provide high school students with important background information on educational preparation, career options and specific job responsibilities as they relate to the profession of pharmacy.

The 12-minute color production, which received rave reviews upon its premiere at the 1985 NACDS Pharmaceutical Conference in Chicago, dramatizes the career decision faced by high school students through a series of flashback techniques which show two young pharmacists exploring various career options during their high school years before choosing pharmacy as the career that is right for them.

Complimentary copies of "The Right Choice" are being sent by Merrell Dow Pharmaceuticals Inc. to NACDS chain members, pharmacy colleges, state boards of pharmacy and national and state pharmacy associations for use in their pharmacy student recruitment initiatives. Questions regarding additional copies may be directed to: The Professional Relations Department, Merrell Dow Pharmaceuticals Inc., 10123 Alliance Road, Cincinnati, Ohio 45242.

NACDS and Merrell Dow Pharmaceuticals Inc. hope the availability of "The Right Choice" will help ensure the brightest possible future for pharmacy and the public which it serves.

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106TH ANNUAL CONVENTION HIGHLIGHTS

"Gateway to Spring" in Greensboro might well be the theme of the 106th Annual Convention of the North Carolina Pharmaceutical Association and Affiliated Auxiliaries to be held April 20, 21 and 22. The Holiday Inn Four Seasons is the headquarters hotel and the majority of activities will take place there.

Joe and Nancy Johnson are the Local Chairmen of the NCPhA and the Woman's Auxiliary functions and Doug Sanders, TMA 2nd Vice President, is Entertainment Chairman for the Traveling Members' Auxiliary.

The Convention begins Sunday, April 20, with the North Carolina PharmPAC Luncheon at 1:00 pm, honoring our three pharmacist-legislators, Barney Paul Woodard, Brad Ligon and Franklin Williams. Convention registration desks will open at 12:30 pm. The NCPhA Awards Session will begin at 4:00 pm recognizing newly qualified members of the Fifty Plus Club, the NC Academy of Pharmacy, the Bowl of Hygeia Award recipient and the Don Blanton Award recipient. The President's Reception will follow this session.

Sunday night activities conclude with the "Opening Session Dinner", when the presidents of the Woman's Auxiliary, the NCPhA and the TMA officially open their respective conventions. James A. Main, Anniston, Alabama, Chairman of the Board of the American Pharmaceutical Association, will be the speaker of the evening. The banquet concludes with the announcement of the 1986 NCPhA "Pharmacist-of-the-Year".

Monday functions for the Woman's Auxiliary include a brunch and tour at Blandwood Carriage House, restored home of former NC Governor John M. Morehead, and a shopping tour of State Street in restored old Greensboro. The TMA Foundation will have a breakfast business meeting. NCPhA members will attend the Second Business Session which includes the Rite of the Roses and reports from committees, the School of Pharmacy and the NC Board of Pharmacy. The Exhibit Program will open at 1:00 pm and close at 7:00 pm with a wine and cheese reception.

Other afternoon choices are the Owens-Illinois sponsored Golf Tournament, the Pilot Life Tennis Round Robin and several workshops. The TMA-sponsored dance from 9:00 pm to midnight featuring Joyce Hawley and the Rhythm Section, so well received at last year's convention will cap the Monday Convention program.

(Continued on page 9)

Nancy and Joe Johnson, Local Convention Chairmen

A century of caring.

UM SÉCULO DE DEDICAÇÃO

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जीवनदान के सौ साल महान

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ETT SEKEL AV OMSORG

GONDOZÁS EGY ÉVSZÁZADON ÁT

قرن من الرعاية الصحية

EIN JAHRHUNDERT FORSCHUNG FÜR LEBEN UND GESUNDHEIT

STO LET PÉČE O ZDRAVÍ

YÜZYILLIK BAKIM

ศตวรรษแห่งความปลอดภัย

VUOSISATA HUOLENPITOA

ΕΝΑΣ ΑΙΩΝΑΣ ΦΡΟΝΤΙΔΑΣ

CIEN AÑOS AL CUIDADO DE LA SALUD

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СТОЛЕТИЕ МЕДИЦИНСКИХ ОБСЛУГ

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Tuesday will find NCPhAers in business meetings from 9:00 am to 5:00 pm, with a needed break for lunch. The Schering Report VII "What's Right with Pharmacy", nominations, resolutions, additional committee reports and a special program sponsored by Pharmacia on "Diagnosis and Treatment of Inflammatory Bowel Disease" will make the day educational and exciting. At least six hours of Continuing Pharmacy Education (CPE) will be provided during the business sessions and workshops. The TMA will hold its Annual Business Session in the morning. The Woman's Auxiliary will also hold a business session in the morning and then be treated to a luncheon at Starmount Forest Country Club. The closing ceremonies will take place at the "Installation Banquet" Tuesday night at which the 1986–87 NCPhA officers will be introduced and installed.

For the second year, the North Carolina Pharmaceutical Association and the North Carolina Society of Hospital Pharmacists will jointly sponsor a Management Seminar. The 6th Annual Joint Management Seminar will also be held at the Holiday Inn Four Seasons for the convenience of those who attended the convention and will begin at 9:00 am on Wednesday, April 23. Six hours of Continuing Pharmacy Education (CPE) will be available at the seminar.

Speakers and their subjects are: Barbara Kramer, Ph.D., "Trends in Health Care and Their Implications for the Health Care System";

Joyce Hawley

Jean Paul Gagnon, Ph.D., "Trends in Health Care and Their Implications for the Pharmacy Care System"; a panel discussion featuring North Carolina pharmacy leaders, "Priorities for Pharmacy"; Larry Shoup, M.S., "Bar Coding, a New Technology Changing the Delivery of Health Care"; Ed Greif, "Managing for Change"; and Pat Chase, M.S., "Promoting Creativity-Skunk Words and You".

SCIENTISTS SPEAK OUT ON NUTRITION AND THE HEALTH OF THE ELDERLY

Despite billions of dollars spent each year by the elderly population on vitamins, minerals, and food supplements, information on the specific dietary needs of older Americans is scarce.

In the January 16th issue of the *New England Journal of Medicine,* Dr. Edward L. Schneider, Deputy Director of the National Institute on Aging, and his colleagues* state that "aging produces important physiologic changes that may affect the need for certain nutrients, vitamins, and minerals." The authors call for more intense and specific research efforts to define the recommended dietary allowances (RDAs) for older Americans.

Since 1943, the National Academy of Sciences' Food and Nutrition Board has published recommended dietary allowances for infants, children, and adults. However, in 1985 the Academy acknowledged the need for better information on which to base nutritional recommendations for the elderly population. This critical lack of information on the relationship between nutrition and aging contributed to the delay in publishing the 1985 RDAs.

"The physiologic features and health status of persons who are 50 to 60 years old are very different from those of persons who are 80 to 90," state Dr. Schneider et al, yet the current RDAs group all people 51 and older into one category. An additional problem, according to the authors, is that RDAs for older individuals are based on data collected from younger individuals.

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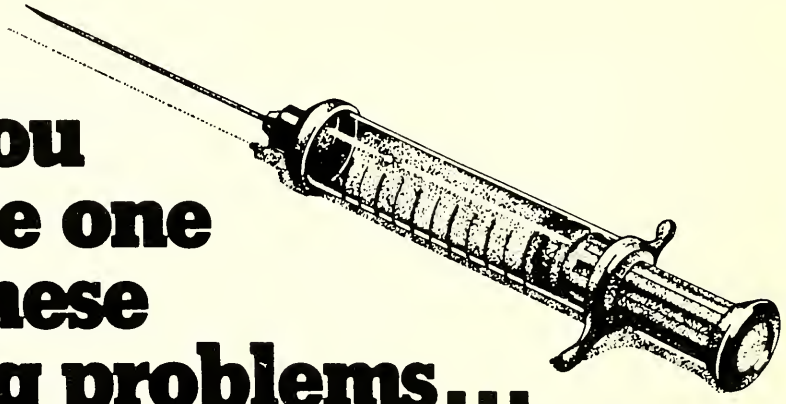
*Eugenia M. Vining, Evan C. Hadley, M.D., and Stacy A. Farnham



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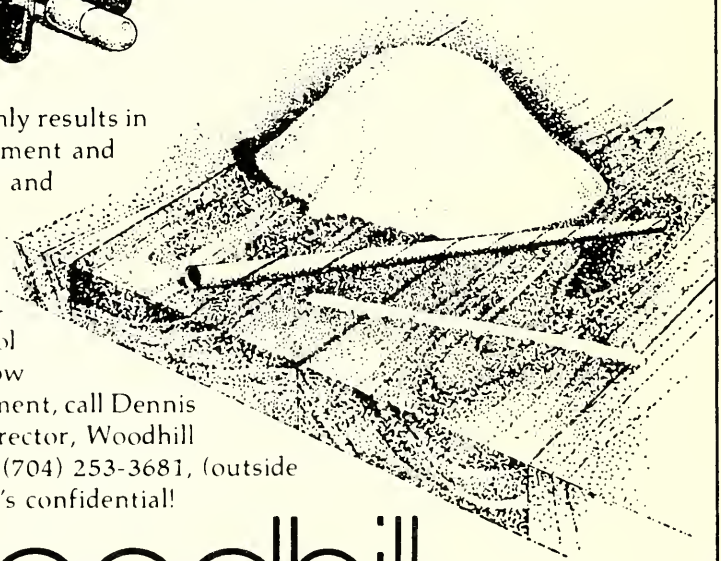

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THE NORTH CAROLINA FAMILY PLANNING PROGRAM

Margaret N. Alexander, M.P.H.
Program Consultant
Family Planning Branch

As a service of the North Carolina Division of Health Services (DHS), the family planning program is concerned with making comprehensive family planning services available on a continuing basis to all persons throughout the State of North Carolina. Family planning services are interpreted broadly to include all medical, social, and educational services necessary to ensure that all persons will have freedom of choice to determine the spacing of their children and the size of their families. Services are provided to approximately 118,000 women through clinics in local health departments and their outlying clinics throughout the state. These services are available to all persons regardless of age, race, sex, socio-economic or marital status, religion, or cultural background who, for one reason or another, cannot obtain these services from a private physician. Patients whose incomes fall below the poverty line are served free of charge. Others are charged based on a sliding fee scale. However, no one is refused care based on the inability to pay. The program is funded primarily through a grant from Title X of the Public Health Service Act and supplemented by reimbursements from Title XIX, Title XX, local and state funds and patient fees.

Each new patient has either a group or individual educational/informational session with a health educator or nurse. This includes information on all birth control methods, instruction in breast self-examination, and some basic instruction in reproductive anatomy and physiology. When the patient chooses a method, the nurse reinforces the information about that method and has the patient sign an informed consent form to be kept in the patient's record. Available methods include oral contraceptives, intrauterine devices, diaphragms, foams, jellies and creams, sponges, condoms and natural family planning.

A comprehensive history is obtained on each new patient and is updated every one or two years depending upon their method of contraception. This history includes social, medical, surgical, menstrual, contraceptive, obstetrical, sexual, immunization, drugs/medications, smoking, douching and family medical histories.

Certain laboratory services are provided to each new patient. These include a hematocrit or hemoglobin, urinalysis for sugar and protein, Papanicolau smears (with repeat smears taken when indicated), culture for N. Gonorrhea, serology for syphilis and rubella antibody titer.

Physicians and/or specially trained nurse practitioners or physician extenders, working under a physician's supervision and standing orders, provide the medical services in these clinics. Each new patient is given a physical examination which includes a palpation of the thyroid, inspection and palpation of the breasts, heart and lung auscultation, blood pressure check, height and weight, abdominal examination, complete pelvic examination including speculum, bimanual and rectal, and other examinations as indicated. This examination is repeated every one or two years depending upon the method of contraception prescribed.

As the family planning patient caseload has increased, so has the need for pharmaceutical services. Pharmaceutical service programs have been established in the majority of the counties in the state and efforts to increase this number is continuing.

As a part of the Title X legislation, monies are regularly set aside for training of state and local staff members. This has been invaluable for training new employees as well as keeping existing employees up to date on changes in the field and new initiatives. Numerous family life education films and materials have been purchased and made available to the citizens of North Carolina through the DHS Film Library and the DHS Mail Room. State, regional and local advisory councils provide guidance and critical evaluation to the family planning program at all levels. They are composed of providers and consumers of family planning services.

From time to time, the federal government sets aside funds to be used for special initiatives that have an impact upon the private sector patients as well as the low income women who are targeted in health department clinics. The Natural Family Planning-Fertility Awareness Initiative is an example. Forty people from across the state have

(Continued on page 12)

been trained as case managers to work with women in both the clinic population and the community at large. Patients who use other methods of birth control can benefit from these techniques because they help them understand why and how their contraceptive methods work.

Another exciting initiative that is currently underway in North Carolina is Preconceptional Health Promotion. Most women do not realize the effect that nutritional habits and the use of alcohol, drugs and tobacco can have on the very early development of a fetus if used prior to and during the early weeks of pregnancy before most women are aware of being pregnant. The Department of Obstetrics and Gynecology, University of North Carolina, has developed a Preconceptional Health Appraisal to identify potential problem areas in a woman's family, medical, reproductive, nutritional and social profile. The appraisal is designed to provide a woman with positive actions that she can take to reduce potential problems or investigate further any problem areas. Four modules (nutritional habits, tobacco use, alcohol use and drug use) are available. These have been tested in nine local health department family planning clinics and are now being made available to other health departments for use in their clinics.

Another initiative that has been used extensively in church and school settings is Postponing Sexual Involvement. This has focused on teaching young people "how to say no" and how to withstand peer pressure as well as to understand the possible consequences of early sexual activity. The Parental Involvement Initiative has been successful in encouraging parental-teen communication about the important issues of growing up. Both of these are community-wide initiatives focused at all parents and teens and not merely clinic patients.

In the most recent session of the General Assembly, monies were appropriated for an Adolescent Pregnancy and Prematurity Prevention Project. These monies will be granted to groups with innovative proposals designed to reach the hard-to-reach teens and prevent unwanted and untimely pregnancies. It is hoped that some of the more successful projects can be replicated in other areas of the state.

For more information about family planning services coordinated by the North Carolina Division of Health Services, call (919) 733-4871 or write to:

North Carolina Division of Health Services
Maternal and Child Care Section
Family Planning Branch
P.O. Box 2091
Raleigh, North Carolina 27602-2091

JOHNSON & JOHNSON WILL CEASE MAKING ALL CAPSULE PRODUCTS

Johnson & Johnson announced that it will no longer manufacture or sell any capsule products made directly available to the consumer, and has no plans to reenter this business for the foreseeable future. The company said it is taking this action because it cannot guarantee the safety of capsules to the degree consistent with Johnson & Johnson's standards of responsibility to its consumers. Further, the company announced plans to replace the capsules now in the hands of the consumers and the trade.

James E. Burke, Chairman of the Board and Chief Executive Officer of Johnson & Johnson, said: "We urge our consumers who use capsules to convert to the new extra-strength Tylenol Caplets, which were specifically designed by the company as a substitute for capsules. The oval-shaped caplet is a solid dosage form that is as easy to swallow as a capsule and is equally effective in relieving pain and reducing fever.

"We take this action with great reluctance and a heavy heart," Burke said. "But since we can't control random tampering with capsules after they leave our plant, we feel we owe it to consumers to remove capsules from the market for the public's protection.

"We are absolutely confident that the consumer preference for Tylenol in caplet and tablet form will keep this brand the most preferred pain reliever in the nation. We fought our way back from the Chicago tragedy in 1982, thanks to the fairness and good judgment of the American consumer. We will do it again this time. In caplets we have a product that we know will be preferred by capsule users over other alternatives," Burke said.

The company said the cost of its decision to halt the manufacture of capsules is estimated to be $150 million. Going out of the capsule business also affects forms of Regular Strength Tylenol, Sine-Aid, Co-Tylenol, Maximum-Strength Tylenol Sinus Medication and Dimensyn menstrual medication.

PHARMACIST KEEPS DOWNTOWN PERKING

by Jim Dumbell, staff writer
Charlotte Observer

The stranger has an early appointment with Joe Miller, pharmacist, artist, jokester, civic leader and a man who may know more people than anybody in Boone.

Just inside Boone Drug the stranger asks for Joe Miller, and this good ol' boy says, "Joe who?" and the stranger figures right there he's in for a time, because Joe Miller owns the place. And then the local laughs and says, "He's in the end booth."

The four men in the end booth stand up and grin all friendly-like and one holds out his hand and says, "Hi, I'm Joe Miller," and the next says, "Mornin', I'm Joe Miller." The third says, "Howdy, I'm Joe Miller," and the fourth says just "Joe Miller." And boy, do they all laugh!

This boothful, and about 50 other people, comprise the Coffee Club, an unorganized conglomeration of locals who hold forth daily at Boone Drug, right in the heart of town. It is a motley assemblage of some 50 or 60 leaders, followers, hangers-on, male, female, young, old, merchants, doctors, college faculty, salespeople, bank-whom work — those who *do* work — in downtown Boone. The coffee is the cement that holds them together. Mostly, it seems, they come for laughs and socializing and to find out what's going on and what's about to go on.

Meetings run from 8:30 to 9:30 every morning, and you get the idea that if you want to buy anything or get anything done in Boone you can just forget it until the coffee hour is over. Although the club is probably older than Joe Miller, he, by virtue of owning the place, is unofficial majordomo thereof.

It's been said that if you want to run for office, get a traffic light or politician placed or removed, need a job for a friend or a name for a baby, seek advice about almost anything or just want a sympathetic shoulder to cry on, you should see Joe Miller.

"Naw," Miller says modestly. "You can't believe any of that."

It turns out that the first of the four who introduced himself as Joe Miller really *is* Joe Miller, the others being blatant imposters just funning a little. Miller, a short, mustachioed man who wears what little hair he has on the sides of his head rather than on top like most people, is a native who works not 15 feet from where he first came into Boone, and for that matter into the world, 46 years ago.

"I was born out in front in the back seat of a Chevrolet," he says. "The doctor's office was right upstairs, and Dad didn't get my mother here in time."

He is sitting where he can keep an eye on the pharmacy counter, and from time to time he hops up to fill a prescription. From time to time a man or woman with an anxious look whispers in his ear. Miller listens attentively, then nods or answers in a low voice.

"He's a soft touch," says Jim Furman, a partner with Miller in three Boone drugstores. "People get to him. He's filled a lot of prescriptions for people he knew couldn't pay for them.

"In dealing with people he's extremely good at putting them at ease. Only you never can tell when he's kidding you. I think it embarrasses him to have people speak of his power. It's not that he uses power so much as he knows who to see, how to present something and how to follow up. He's more interested in advancing the cause of Boone than of some individual politician, say."

(Continued on page 14)

Joe Miller

Real estate agent Jerry Coe, a regular at the Coffee Club, stops short of saying the destiny of Boone, and to an extent Watauga County, are decided in Boone Drug, but he adds significantly, "A lot of things are discussed there, and Joe doesn't seem to take too strong a part in presiding over things but, well, a lot of things get discussed. Joe's been instrumental in holding downtown together since the mall came.

"And every time (U.S. Rep. Jim) Broyhill comes to call on his constituency he makes the drugstore his main meeting place. Joe's a real asset to Boone. I doubt if the guy's got an enemy.

For someone who constantly kids his friends, as Miller does, that's a tribute. Cecil Greene, president of Farmers Hardware in the next block, remembers the time Miller put a sign in the drugstore proclaiming, "Cecil Greene's having a Christmas sale. He has most things marked down to retail."

From time to time Miller handletters 60 cardboard signs and hangs them from the ceiling in the drugstore. Many are cogent admonitions, such as, "Listen to others as you would have them listen to you;" "A speedy car and a little liquor will make your wife a widow quicker;" and, "When in doubt, mumble. When in trouble, delegate."

At the coffee hour, Miller says, "everything's discussed. Always a lot of politics. People say what they think, but there's never any real falling out. We have so much fun in here. There's always laughter. Always somebody with a joke or story. But if somebody had a problem, I can remember someone taking up a collection to help them. I remember one woman had terminal cancer and the collection came to $500. Two or three times I've seen people put in $100 bills."

Among the items found in Boone Drug is a counter of artist's supplies. That stems from an activity Joe Miller took up three years ago — watercolor painting. He has done well enough at it to be represented in several regional galleries, to have six paintings in Jack Nicklaus's house at Elk River, to teach several art students and to have sold "quite a few" paintings at prices ranging from $150 to $550. He says his goal is to be in a major gallery in five years.

Periodically Joe Miller emcees an informal little celebration of a member's birthday, and this day he excused himself to do so.

While he was gone, a stooped, somewhat pathetic-looking character appeared from behind a counter. Long, black hair spilled beneath his top hat onto what looked like a Salvation Army jacket. he had the forlorn appearance of a lost cocker spaniel. Musical notes, but definitely not music, came from a small accordion clutched to his chest. In the other hand he held an imitation birthday cake, a Moon Pie with one small candle in the center.

There was something vaguely familiar about the little figure. There should have been. It was Joe Miller.

A pharmacy family: Left to right, Cliff and Linda Butler, Chapel Hill, and Ernestine and Herman Lynch, Dunn, Linda's parents. Photo by Colorcraft at the 1985 Annuam NCPhA Convention

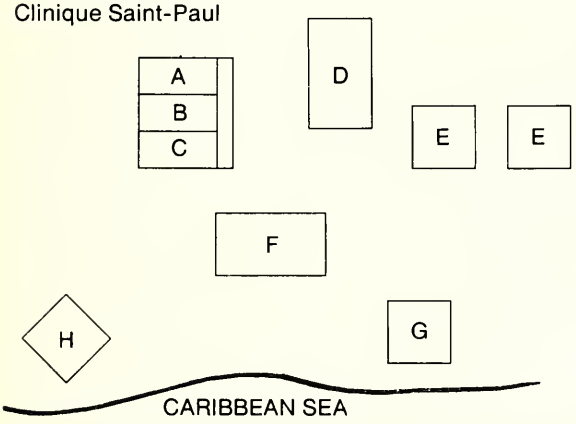
PHARMACY PRACTICE IN A RURAL HAITIAN CLINIC

Last spring break, March 1-10, the Chapel of the Cross Episcopal Church in Chapel Hill, North Carolina, sent a medical mission team to the town of Montrouis on Haiti's western coast. The Reverend David D. Stanford, associate pastor at the Chapel of the Cross, organized and coordinated the mission team. Advance preparation for the mission included weekly classes on Creole (Haiti's national language), organizational meetings, and fund-raisers. The team, which consisted of three doctors, one dentist, two parasitologists, and students in all fields of medical science, was only one group among many which visits the Montrouis clinic yearly to help it provide health care to the people of the region. I was fortunate enough to be asked by Reverend Stanford to act as clinical pharmacist for the team.

People began to line up outside the clinic at 5:30 am, and by the time we opened the doors some three hours later, the line had grown until it filled both the clinic waiting hall and the benches in the courtyard outside. Word had spread, even up into the mountain villages, that a group of *blancs* (whites) from the United States had arrived at Clinique Saint-Paul. Now, rather than depending on voodoo priest-doctors for medical help, the people could be seen by providers of modern medicine. Although in high demand, Western medicine has had a limited impact on Haiti because of a serious lack of availability. The shortage of trained medical personnel has led to the widespread use of *houngans* (voodoo priests) as health care providers for many towns and villages. Consequently, to a Haitian, a physician, nurse, or pharmacist is a rare and valuable individual whose services must be taken advantage of when available. In that light, it is understandable that the villagers kept coming to Clinique Saint-Paul for six to ten hours per day, and waited their turn in the tropical March sun; just the knowledge that the blancs could help them made their wait worthwhile.

As shown in Diagram 1, the Saint-Paul compound itself is comprised of two clinical buildings plus a chapel, an open-air refectory, and quarters for the pastor, his seminarians, and for the medical teams that visit throughout the year. The two medical buildings consist of a dental clinic and a medical building. Inside the medical building are a pharmacy, three small examination rooms for physicians, and a laboratory. A typical patient had to wait approximately two hours in the courtyard or waiting room/hallway until his name was called. Then his temperature and blood pressure were taken and he was sent to an examination room. After the initial diagnosis, the physician could order blood tests from the lab nextdoor (our lab team had results back in an average of five minutes or less). After interpreting lab results, the doctor prescribed medicine for the patient. If no special medications were needed, the doctor almost always prescribed him vitamins. Due to the lack of adequate nutritional foods, almost every patient receives at least multi-vitamins after a visit to the doctor — in Haiti, it is a policy, and a good one, that no one leave the clinic empty-handed. By far, the most frequently prescribed medicine in our clinic was chloroquine, as malaria is endemic throughout all

Diagram I:
Clinique Saint-Paul



A Laboratory
B Examination rooms
C Pharmacy
D Dental clinic
E Dormitories
F Refectory
G Chapel
H Pastor's quarters

(Continued on page 16)

of Haiti. Other frequently prescribed drugs included penicillins, sulfonamides, aspirin, acetaminophen, nitrofurantoin, and anti-infectives such as thiabendazole, metronidazole, and mebendazole.

The Haitian system of dispensing involves the use of plain white envelopes and glass bottles. Solid dosage forms are placed in an envelope and the directions are drawn, not typed or written, on the front. Due to the high level of illiteracy, this practice, unfortunately, is necessary. Circles drawn on the envelope front tell the patient how often to take the medication. One circle means to take the medication once per day; two nonadjoining circles mean to take the medicine twice daily,and so on. And if two circles are drawn affixed to each other, then two tablets are to be taken at the same time. Referring to Diagram 2, if the physician directions specified one tablet twice daily, the envelope would appear as in figure A. If the physician specified two tablets three times daily, the envelope would appear as in figure B. Liquid dosage forms are placed in empty glass bottles that are supplied by the patient; consequently, most patients bring bottles with them when they visit the clinic. With liquid medications, only word-of-mouth directions are given, but most Haitians know to repeat the directions back to the pharmacist once or twice before leaving for home.

There is a strong need for prescription medications in Haiti year round. Due to the tropical climate and the high humidity, Haiti is a strong breeding ground for insect vectors of many infectious diseases. This situation, coupled with the lack of clean water and the nutritionally inadequate diet of the people, explains the high frequency of use of antibiotics and anti-infectives mentioned earlier. Even with the use of these agents, the average life expectancy for Haitians is only 47 years of age, and only one out of very five live-born children lives past the age of five. These statistics became reality for us during Sunday morning service at the church, Legliz Saint-Marc; out of an entire congregation of several hundred people, there were only six elderly Haitians. And the value placed on these six was very evident; they were allowed to sit in chairs in the center of the church directly in front of the altar, and were the first to receive communion or to exit the

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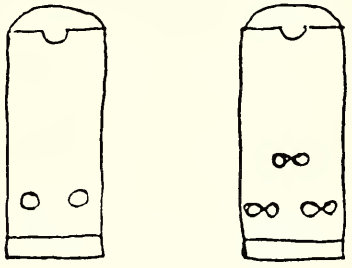
church. A related observation from a pharmaceutical standpoint was the low use of high blood pressure medicines. This may be due to the lack of people of geriatric age, or to the quiet and peaceful lifestyle of the Haitians, or possibly to both. Whatever the case, the most popular drugs in the United States (antihypertensives) sat on the pharmacy shelves in Montrouis and expired because there was no use for them in the village.

The Haiti Mission Tour was truly a worthwhile experience, and I believe that everyone involved with the trip received as much as he or she gave. Personally, I would like to thank the members of three groups for their advice, support, and concern: the Pharmacy Foundation, the North Carolina Pharmaceutical Association, and the groups that comprise the Pharmacy Senate, especially Kappa Epsilon and the Student National Pharmaceutical Association. The knowledge that others in the field of pharmacy are also interested in the medical needs of the people of Haiti has been a great help to me.

David R. Blanchard

Dec 1985 Graduate
UNC School of Pharmacy

Diagram 11:
Due to the level of illiteracy in many small villages, medication directions must be drawn graphically on small envelopes.



Take one tablet two times daily.
A

Take two tablets three times daily.
B

Members of the staff

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POTASSIUM DEPLETION AND REPLACEMENT THERAPY

Nancy S. Fortson, Pharm.D.
Clinical Pharmacist
Charlotte Memorial Hospital and Medical Center
Beverly Holcombe, Pharm.D.
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Potassium, the primary intracellular cation in body tissues, is necessary for cellular metabolism including protein and glycogen synthesis. Maintenance of the ratio of intracellular to extracellular potassium concentration is necessary for neuromuscular and cardiac function. Total body potassium stores are approximately 3000-4000mEq of which 98% is found intracellularly (160mEq/L) and 2% in the extracellular and plasma compartments (3-4mEq/L). A serum potassium determination, usually the only available indicator of potassium status, is actually a poor reflector of a patient's total body potassium. Although extracellular potassium is a small percentage of total body potassium, derangements in its concentration can greatly affect neuromuscular function.

Potassium balanced is regulated primarily by the kidney. This balance of total body stores is maintained even though dietary intake varies. Greater than 90% of ingested potassium is eliminated from the body in urine. Potassium is filtered at the renal glomerulus and reabsorbed in the proximal tubule and loop of Henle. Excretion of potassium results from secretion into the distal tubule and collecting duct. Urinary potassium excretion ranges from 5-1000mEq per day. Maximal renal excretion is accomplished only after several days of high potassium intake, whereas maximal sodium excretion occurs within a few hours of an abrupt sodium load. Even in the face of a potassium-free diet, potassium excretion ranges from 5-20mEq per day. Other factors including aldosterone, urine flow to the distal tubule, sodium intake, and acid-base status affect the renal conservation or elimination of potassium. Daily losses in feces (5-10mEq) and sweat (0-20mEq) are small.

Serum potassium concentration is affected by other internal factors including insulin and acid-base status. Insulin causes a shift of potassium from the extracellular space into hepatic cells and skeletal muscle. This is commonly seen in patients receiving parenteral nutrition. Alkalosis also results in a redistribution of potassium from the extracellular fluid into cells. In alkalotic states H^+ ions are released into the extracellular fluid in order to lower extracellular pH. To maintain electroneutrality potassium shifts intracellularly resulting in a decrease in serum potassium concentration. For each 0.1 unit increase in arterial pH there is approximately a 0.6mEq/L) reduction in serum potassium concentration. The converse is true for acidemia.

There are three potential sources of potassium depletion: decreased intake, increased renal excretion, and increased extrarenal losses.

Decreased Dietary Intake

The normal range of dietary potassium intake is 50-150mEq per day. As discussed previously, the kidney can lower potassium excretion to a minimum in order to maintain potassium homeostasis. Therefore reduced intake does not result in potassium depletion unless intake is severely restricted.

Increased Renal Excretion

Among the influences on renal potassium excretion is the urine flow to the distal tubule. Diuretics promote potassium wasting by inhibiting sodium chloride and water reabsorption proximally which results in an increased flow to the distal tubule and potassium secretion. The use of diuretics for the treatment of edema-forming states commonly leads to total body potassium depletion. However, the treatment of mild, uncomplicated hypertension with diuretics infrequently causes significant depletion of potassium.

The mineralocorticoid hormone, aldosterone, acts on the distal tubule and collecting duct to increase sodium reabsorption and potassium and hydrogen secretion into the lumen. Ingestion of large amounts of licorice, primary or secondary hyperaldosteronism conditions with high renal output, and Cushing's syndrome may produce mineralocorticoid excess resulting in potassium depletion.

The presentation of sodium to the distal tubule accompanied by a poorly reabsorbable anion,

(Continued on page 21)

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that is an anion other than chloride, results in sodium reabsorption and enhanced potassium excretion. The administration of ticarcillin or carbenicillin may result in hypokalemia via this mechanism. Metabolic alkalosis, secondary to the acid loss with vomiting or gastric suction, also increases renal potassium excretion.

Increased Extrarenal Losses

Although fecal losses of potassium are small, the presence of diarrhea can result in losses as great as 300mEq per day. Gastrointestinal losses of potassium associated with vomiting, gastric suction, intestinal fistulas, or chronic laxative abuse may also result in total body potassium depletion. Chronically increased sweat production that occurs with excessive exercise in a hot climate can result in significant potassium losses.

Clinical manifestations of hypokalemia are related to its effects on the skeletal and smooth muscle and cardiac conduction. Most individuals can tolerate a 5% loss of total body potassium without clinical consequences. Muscle weakness does not usually occur until the serum potassium concentration is less than 2.5mEq/L. Weakness of the lower extremities occurs first. In severe potassium depletion paralysis of the respiratory muscles and respiratory failure may ensue. The smooth muscles of the gastrointestinal tract can be involved producing an ileus with symptoms of anorexia, nausea, vomiting, and constipation. Potassium depletion can affect a variety of renal functions. The most noted effect is a reduced ability to concentrate urine resulting in polyuria and polydispsia. EKG manifestations of hypokalemia include depression of ST segments, flattening and inversion of T waves, and increased height of U waves.

Potassium replacement is indicated in the presence of a serum potassium concentration less than 2.5-3.0mEq/L. Replacement therapy is also necessary if there are EKG manifestations of hypokalemia in the presence of a mild deficit. Therapy must be directed at treating the underlying disorder as well as increasing the intake of potassium.

Since serum potassium concentration has no definite correlation with total body stores, only a rough estimate of potassium deficit can be made. Generally, a serum concentration of greater than 3.0mEq/L potassium requires 100-200mEq of potassium to increase the serum concentration 1.0mEq/L. However, when the serum potassium concentration is less than 3.0mEq, potassium doses of 200-400mEq may be necessary to increase the serum concentration 1.0mEq/L.

Although dietary supplementation with foods rich in potassium (orange juice, bananas, dates, etc.) may seem preferable it can be more expensive than oral supplements. Various potassium preparations are available for intravenous and oral use, including Cl^-, HCO_3^-, acetate, citrate, phosphate, and gluconate salts. The chloride salt is the preferred potassium supplement for most patients because metabolic alkalosis is often associated with hypokalemia and chloride achieves a greater increase in the serum potassium concentration. This is especially important in patients on a low salt diet and receiving diuretics for the treatment of hypertension. In certain patients with potassium depletion and metabolic acidosis, another potassium salt (HCO_3^-, citrate, acetate) may be preferable.

Many of the derangements associated with hypokalemia are not life-threatening so potassium replacement may be given orally. Therapy is usually accomplished by 20-40mEq of potassium taken by mouth three to four times per day. Monitoring of serum potassium concentration should be done during potassium replacement therapy. Oral potassium products are available as liquid, effervescent tablets, powders, timed-released capsules, enteric coated tablets, and wax-matrix tablets. Enteric coated tablets have been associated with a high incidence of small bowel ulcerations. Patients prescribed potassium liquids, powders, or effervescent tablets should be advised to take the product in four to eight ounces of water, juice, or other beverage and sipped slowly to avoid gastrointestinal distress. It is also important to warn patients taking wax-matrix tablets that once the potassium is released the unabsorbable matrix may appear in the stool.

Patients with severe hypokalemia or those unable to take oral products must be given potassium intravenously. Most potassium deficits can be corrected by 40mEq of potassium chloride added per liter of non-dextrose maintenance infusion fluid or administered over two to four hours. A non-dextrose solution, which does not stimulate insulin, is preferred to avoid a fall in serum potassium concentration during replacement therapy. The rate of intravenous potassium administration in adults should generally not exceed 10mEq per hour or 150mEq per day. In life-threatening complications of hypokalemia potassium may be infused at doses of 40mEq or

(Continued on page 22)

greater per hour. In these situations close monitoring of serum potassium concentration, muscle strength and the electrocardiogram is mandatory. Rapid intravenous administration of potassium may result in EKG findings consistent with severe hyperkalemia such as peaked T waves and widening of the QRS complex. It is recommended that the concentration of intravenously administered potassium not exceed 40mEq per liter of fluid because it is irritating to the vein and may cause phlebitis.

Maintenance of total body potassium stores is necessary for many cellular functions including neuromuscular and cardiac function. Although the kidney is an excellent regulator of potassium balance, depletion may result from decreased intake, increased renal excretion, or increased non-renal losses. Potassium replacement therapy can usually be accomplished by oral supplementation. Severe hypekalemia may necessitate intravenous potassium therapy. Both therapeutic modalities require close monitoring of serum potassium concentrations and the patient's clinical response to therapy.

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RESOLUTIONS ADOPTED AT THE 105 ANNUAL MEETING, RALEIGH

RESOLUTION #1

Title: Resolution of Appreciation

Whereas, the 1985 Annual Convention of the North Carolina Pharmaceutical Association and Affiliated Auxiliaries has been most successful, and

Whereas much of the success has been due to extensive planning and participation by the Wake County Pharmaceutical Association and the Wake County Auxiliary and the members of the TMA in Wake County, and

Whereas the job of planning the Convention was done by Jerry White, Woman's Auxiliary Local Chairman and Al Lockamy, NCPhA Local Chairman, therefore

Be it resolved that this resolution of appreciation be sent to Mrs. White and Mr. Lockamy with the grateful thanks of all who participated in the Convention

From the Committee

RESOLUTION #3

Title: Elimination of Sampling of Controlled Substances

Whereas, there is a growing problem with legal controlled substances finding their way into the illegal market, and

Whereas many pharmaceutical firms do provide samples of controlled substances to prescribers through their sales representatives, and

Whereas these representatives do not go through any special screening or licensing process to have these controlled substances in their possession and available for distribution, and

Whereas the Drug Enforcement Agency rarely checks these representatives' records, which may encourage these records to be improperly kept and maintained;

Therefore be it resolved, that the North Carolina Pharmaceutical Association encourage every effort to prohibit the sampling of controlled substances in North Carolina, and

Be it further resolved, that the North Carolina Pharmaceutical Association work with the appropriate state agency to implement this action.

From the Committee

RESOLUTION #5

Title: A Resolution of Thanks to Convention Supporters

Whereas, the success or failure of a Convention depends significantly on support received from manufacturers, suppliers and exhibitors, as well as convention participants, and,

Whereas many companies have supported the 1985 Annual Convention of the North Carolina Pharmaceutical Association and Affiliated Auxiliaries through contributions of money, programs, gifts and prizes, as well as being a part of the Exhibit Program, and

Whereas the programs of this Convention have been well-planned and delivered much valuable education to improve the practice of pharmacy by those attending, therefore

Be it resolved that letters of thanks be sent to all companies, individuals and organizations who helped provide quality programs, gifts and prizes for this year's convention, and

Be it further resolved a list of these companies be published in the *Carolina Journal of Pharmacy.*

From the Committee

RESOLUTION #6

Short Title: Payment for Patient-Oriented Services

Whereas changes occurring in the health care marketplace require that pharmacists become aware of new opportunities to market and obtain reimbursement for patient-oriented services, and

Whereas many pharmacists do not have the necessary time and resources to develop and market such services, and

Whereas there are pharmacists in the state of North Carolina who are providing patient-oriented services and receiving reimbursement for these services,

Be it resolved that, the NCPhA take appropriate action to identify patient-oriented services which are being reimbursed in North Carolina, the individuals who are providing such services, and the best means for implementation and marketing of these services, and

Be it further resolved that, the NCPhA make this information available to the membership of NCPhA through a directory or some similar form of communication.

(Continued on page 24)

From the Committee on Community Pharmacy

RESOLUTION #7

Short Title: Pharmacy Response to Alternative Health Care Plans

Whereas HMOs, PPOs and similar alternative health care arrangements are rapidly increasing in number in the health care marketplace, and

Whereas the patient enrollment in HMOs alone is expected to triple by 1990, encompassing 30-50% of the U.S. population, and

Whereas competition from HMOs and exclusive provider arrangements is adversely affecting community pharmacies in many areas of the country, and

Whereas in several states, pharmacists have become organized through the state pharmacy associations to offer cost containment measures, other than pharmacy fee reduction, to providers of health care insurance.

Be it resolved that, the NCPhA study the impact of HMOs and PPOs on pharmacy in North Carolina, and alternative means by which pharamacists can become organized to effectively compete with them, and

Be it further resolved, that the NCPhA take a leadership role in this endeavor

From the Committee on Community Pharmacy

RESOLUTION #8

Title: Polygraph Testing

Whereas, The profession of Pharmacy has been shown by recent surveys to be the most trusted of all the professions, and

Whereas a pharmacist must pass rigorous courses of study and examinations, and must meet high standards of morality and,

Whereas polygraph tests have been shown to be inconclusive and inadmissible as evidence in North Carolina courts, and

Whereas the inaccuracies of these tests because of the reactions of the tested individual and improper interpretations by the examiner resulting in dismissal or failure to be hired can give a professional an undeserved bad reputation, therefore

Be it resolved that the North Carolina Pharmaceutical Association condemn the use of polygraph examinations as a preemployment screening tool, and

Be it further resolved that the North Carolina Pharmaceutical Association seek to have laws passed prohibiting such use of polygraphs.

From the Committee

LOAN FUND

The TMA Loan Fund is one of many separate funds which comprise the Consolidated Student Loan Fund administered by the North Carolina Pharmaceutical Association. Loans up to three hundred dollars a semester are made to undergraduate pharmacy students to help meet unexpected living or school expenses. For more information about how you can establish or contribute to an existing loan fund, contact the NCPhA office.

October 17, 1985

Dear Mr. Collins,

I am a recent recipient of a North Carolina Pharmaceutical Association Consolidated Pharmacy Loan. I am writing this note to thank you for making this possible.

I am 30 years old and already have a B.S. degree and therefore am not eligible for Bell Grants etc. . . . My only funding for pharmacy school has been through the College Foundation and whatever money I can get through working etc. . . . At the present time I am on rotation and am very financially strapped. This loan will help a great deal toward removing some of this financial burden.

Thank you very much.

Name Withheld

Dear Mr. Collins:

Please excuse the informality of this letter, but time is precious this week and I'd better make use of the materials at hand to write you while I have the chance! Besides, I have a two year old at home and whenever Mommy writes a letter Robert insists on including his artistic endeavors wherever possible.

Yes, I am very much in need of the wonderful loan I received last week through the Institute of Pharmacy here in Chapel Hill. Even though I must eventually repay it, it feels like a gift. It is so nice to have something go smoothly for once!

I am a wife, mother and student. Jostling these roles is very difficult at times — money problems don't help our days flow smoothly. Thanks to your generosity a few of the rough spots have been patched.

Thank You Very Much
Name Withheld

DICKINSON'S PHARMACY

by Jim Dickinson

Mail-order: a disaster waiteth. "It's a big business, and getting bigger," my lunch companion from industry said. "They're doing over $20 million a year.

Nothing could stop it, he said. We were talking about mail-order prescriptions, and the way some of the big drug chains are getting into it. To help everything along, mail-order prescriptions are being offered as an attractive option to cost-beseiged employers by third-party programs such as PAID Prescriptions, recently acquired by Porex Technologies Corporation, owner of the vast Medco (National Pharmacies) mail-order house.

In addition, the 17 million-member American Association of Retired Persons/National Retired Teachers Association mail order prescription drug operation in Washington, D.C. has long been the biggest single prescription processing center in the country.

The over-65s age group is the fastest-growing age group in the country, and by the year 2025, more people will be middle-aged to elderly than will be young.

All of which adds up to a cosmic chain-reaction atomic boom in mail order prescriptions, right? You betcha — I'm buying all the stock I can get my hands on.

And why not — poor old Grandma, who can't afford $100-per-pill biotech miracle arthritis cure-alls that we're now inventing because zero-deficit Gramm-Rudman federal spending levels won't raise her Social Security or extend Medicare to ambulatory Rxs, has to get her low-cost medications without walking to the drug store — which means the mail-order option. Right?

Even if she could suffer the pain in her joints enough to stagger out to the HMO or chain drug store two bus sections away from her high rise, she'd probably get mugged by unemployables on the way — which is further grist to mail-order Rx mill. Right?

Lots of people who think they're close to where it's at see this as clearcut scenario for our future, just a few years from now.

That's really the bottom line as to why legislative action against mail-order prescriptions is so hard to get started. In addition, there are other obvious reasons — for-profit independent pharmacists charge more per Rx than mail order houses do, and everything they say on this subject is biassed in their own economic interest, so it can be disregarded.

Also, we don't have a body-count we can lay on the mail-order houses' doorsteps.

Not yet, we don't. But as a society, we're working on it. It'll soon be here.

Nobody wants to see it, and those anti-mail-order protagonists out there would all wish that they could win their point without a body-count, but the political/public opinion battlefield will demand solid proof before it sanctions this particular form of restraint-of-trade.

So look for bodies. They'll come in the following ways:

(1) As mail order programs begin competing with each other, the mail order option will get into the color supplements of the Sunday papers. Ours is better, faster than theirs — our patient profiles protect you against interactions whereas they don't have any. After a while, traffickers and junkies will figure out that the mailboxes in the old-folks' appartments across the way have drugs in them.

(2) Mail carriers will get robbed, drawing more publicity to this problem. Controversy will

(Continued on page 26)

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start on whether "certain" mailmen on particularly hazardous routes should carry guns, go in pairs, or be accompanied by attack dogs.

(3) The wrong people will accidentally get mail-delivered prescriptions — e.g., a visiting grandchild, mental incompetents, etc. — and there will be more reported deaths from this cause than at present (there are some, now).

(4) Drugs will get contaminated by Postal Service mechanized handling and occasional mishaps (broken containers, loosened closures, become subject to unusual temperature/moisture/smoke/volatile gases in environments sometimes encountered by the mails.

But until any of these things actually happen, and there is an actual body-count to bring before Congress and/or the state legislatures, all this is simply defamatory theory, uttered only for selfish reasons by those who stand to gain economically if mail-order prescriptions and all their many public benefits are in any way restricted. Understand?

This feature is presented on a grant from Mylan Pharmaceuticals, in the interests of promoting the open discussion of professional issues in pharmacy. Mylan Pharmaceuticals accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of Mylan Pharmaceuticals.

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(Continued on page 28)

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HAWAII CHANGES RECIPROCAL STATUS

Applications are now being accepted and processed that will enable pharmacists licensed in Hawaii to obtain reciprocal licensure in every state except Florida and California. In the same action, pharmacists licensed in every state except Florida and California will be able to obtain reciprocal licensure in Hawaii.

Hawaii has been an associate member of the National Association of Boards of Pharmacy (NABP) since 1960. As stated in NABP's constitution, in order for a state to change its membership status from associate to active, it must permit reciprocal licensure. The only U.S. states that now remain as associate members of NABP are Florida and California.

As stated in its constitution, NABP believes in standard licensure requirements. These standards enable pharmacists to have freedom of mobility, according to Fred Mahaffey, NABP Executive Director.

In a telegram to Jerold Sakoda, executive secretary of the Hawaii Board of Pharmacy, NABP President Martin Golden said that he is pleased Hawaii has entered into active membership in NABP.

For more information on the reciprocal licensure process, contact NABP.

NABP is a non-profit, voluntary organization whose membership consists of each of the boards of pharmacy in the United States, the Virgin Islands, Puerto Rico and several provinces of Canada. Its purpose is to provide for reciprocity in pharmaceutical licensure in the United States based upon a minimum standard of pharmaceutical education and to improve the standard of pharmaceutical education, licensure and practice by cooperating with state, national and international agencies having similar objectives.

Juliana Smith, Class of 1984, received two achievement awards from the Dista Products Company, Division of Eli Lilly and Company at a recent eastern regional meeting in Connecticut. She was selected to the Regional Rookie Team (less than 2 years of service with Dista) in recognition of her achievements in sales. Additionally, she received the Area Achievement Award representing the Raleigh area for her accomplishments during 1985.

LOCAL NEWS

CHARLOTTE WOMAN'S PHARMACEUTICAL AUXILIARY

The January meeting of the Charlotte Woman's Pharmaceutical Auxiliary was most interesting and informative. Cathy Wilkins, Consumer Education Representative of Duke Power Company, demonstrated the use of Microwave cooking.

Mrs. Jesse Oxendine, president, presided. Mrs. W. B. Hawfield gave the devotional. Mrs. Gibbs Henley, treasurer, reported that an afgan project, sponsored by Mrs. Johnie Bennick, netted a profit of $277.00. The sale of Christmas trees, courtesy of Mr. and Mrs. Jesse Oxendine, netted $539.50. The money goes to support scholarships to the School of Pharmacy at Chapel Hill.

Twenty members and guests attended the noon luncheon meeting at the Y.W.C.A.

Dr. Howard Glazer, pharmacy coordinator of Area Health Education Center, discussed "What's New in Pharmacy" at the February meeting of the Charlotte Woman's Pharmaceutical Auxiliary. Mrs. Leslie Davis, first vice president, introduced Dr. Glazer and his wife, Meredith. Dr. Glazer recently moved to Charlotte from Ann Arbor, Michigan, where he was assistant professor of pharmacy at the University of Michigan and Clinical pharmacist, University of Michigan Hospitals Outpatient Clinics.

Mrs. Jesse Oxendine, president, presided at the luncheon meeting held at the Y.W.C.A. Mrs. Robert Lewis provided attractive Valentine decorations. Mrs. Tobie Steele gave the devotional. Mrs. Don Smith announced plans for the Auxiliary's annual "Fun Day" to be held at the Idlewild Country Club in March.

Corresponding secretary,
Virginia Steele

JOHNSTON COUNTY

Newly installed officers of the Johnston County Pharmaceutical Society are Carlyle Woodard — president; Tina Hobbs — vice president; and Ben Pell — secretary treasurer. These officers were installed at the January 14 meeting of the Society by NCPhA Executive Director Al Mebane, who was rewarded with a Johnston County ham. Appropriate?

ALAMANCE COUNTY

1986 officers of the Alamance County Pharmaceutical Association installed Wednesday night, January 22, are Dale Thompson — president; David Hix — vice-president and Jack Watts — secretary-treasurer. Al Mebane, NCPhA Executive Director, conducted the installation ceremonies and gave a brief talk on the NCPhA sponsored PPO.

SANFORD

The Lee County Pharmaceutical Association was founded January 23, 1986, at a meeting held in the Central Carolina Hospital conference room. Officers elected and installed were Kevin Almond — President; Billy Cameron — Vice president and Beth Hough — Secretary treasurer. A proposed Constitution and ByLaws was presented to be reviewed and adopted at the next meeting.

GOLDSBORO

The Wayne County Pharmaceutical Society held its Officers Installation banquet at the Steak Barn Sunday night, January 12. 1986 officers installed were Bill Kesler — President; Vance Wood — Vice President; Louise Kesler — Secretary and Bob Edwards — Treasurer. Members of the Executive Committee were Tonya Uzzell, Buzz Baker and Neal Fowler. Al Mebane, NCPhA Executive Director was the speaker and installed the new slate of officers.

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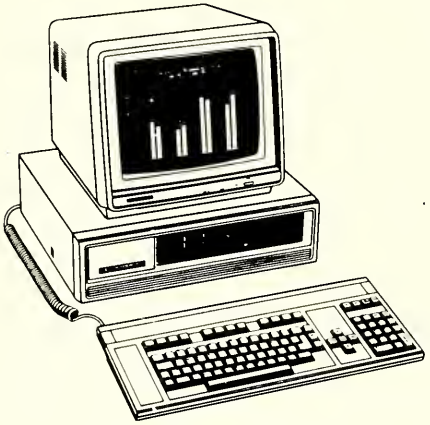

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ADVANTAGES OF WALKING BRISKLY AT WORK AND AT HOME

(from THEME, a publication of Pilot Life Insurance Company)

Some people, including Dr. Boyd Lyles, cardiac rehabilitation director of the Aerobic Center in Dallas, believe that proper walking burns more calories and exercises more muscles than jogging. Besides, walkers don't suffer serious leg and knee injuries. More and more people are learning that walking is the quickest and safest route to fitness. Aside from speed, the major difference between walking and running is that at some point, runners have both feet off the ground. So runners land on one foot with their total body weight. On the other hand, with walking you always have one foot on the ground, so your body never absorbs that kind of shock.

Consider some of the advantages of walking:

- It strengthens bones and organs, including the heart.
- It creates a booster heart action to support the cardiac pumping (each calf muscle becomes, in a sense, an auxiliary heart).
- It is safe, efficient, cheap, and can be followed throughout life.
- It exercises the whole body by working almost every muscle.
- It improves circulation, digestion, and elimination.
- It is so much more convenient than jogging, swimming and bicycling (you can walk almost anywhere with no change of clothes or additional equipment needed).
- It can lower blood pressure and reduce the risk of heart attack and stroke.
- It can lubricate the joints, reducing the pain of arthritis.
- It helps develop collateral coronary-artery circulation (this can lessen the severity of a heart attack and improve recovery after one).
- It is a natural tranquilizer and helps a person sleep better.
- It reduces stress and tension and cuts back the number of headaches.
- It can help us get out of a depression.
- It sharpens our sense perception and alertness.
- It is a sure-fire way to lose weight. (Walk briskly an hour a day and, in a year's time, you can lose 15 to 30 pounds if your intake of food remains the same).

Leon Summit, a New York based free-lance medical writer, in a great article on walking in the magazine, *Modern Maturity*, makes an excellent point. He says, "There is an especially valuable cardiac benefit from walking that few people know about — it helps relieve an enormous pumping burden imposed on the heart by our upright posture and long legs." When the calf muscle contracts, it exerts a push on the blood in the vein and pumps it up toward the heart. When the calf muscle relaxes between steps, valves close and keep the blood from slipping back down. Each step pushes more blood toward the heart. Each leg is like an auxiliary heart. This increases the flow of fresh, newly oxygenated blood to the whole body, but especially to the brain. Every ounce of "used" blood has to be pumped all the way up from the feet to the heart and lungs for reoxygenation and recirculation. This is why standing at attention in the military often brings about a situation where the soldier faints from lack of oxygen in the brain. Sitting too long at a desk or in a plane can pool our blood. But when we walk, the two booster hearts, one in each leg, help the heart to do its pumping job. These leg boosters, when in action, make the heart's work a piece of cake. The heart works less when you walk than when you stand at attention or sit slouched in an office chair. It pays to walk regularly. A little walk of ten feet is better than no walk at all.

Is it far fetched to say that the executive who manages by walking around has an edge in brain power over his sedentary peer? It isn't. The walking executive has a much richer flow of blood to the brain which helps his or her sensing, perceiving, remembering, imagining, thinking, deciding and acting. I know you are supposed to beware of anything that sounds too good to be true. This is an exception — walking *is* really this good, both at work and at home.

HENRY LEWIS SMITH and Tracey Fodor Larimer were married Sunday, February 16, 1986 at the Fountain Baptist Church, Fountain, North Carolina. Henry is vice president of Carolina Medical Products and Tracey is director of marketing. He is a 1972 graduate of the UNC School of Pharmacy and former secretary treasurer of NC PharmPAC. The Smiths will be moving to Farmville where the new facilities of the company are located.

OBITUARIES

BAYLUS CADE BROOKS, O'Brian, Florida, died Wednesday, January 22, 1986 at the age of 70. He was a former president of the North Carolina Pharmaceutical Association and former owner of Fayetteville Drug Company and Bordeaux Drug Company. In 1975 he received the A.H. Robins "Bowl of Hygeia" Award for outstanding service to his community and in 1976 was selected as the North Carolina Pharmaceutical Association "Pharmacist-of-the-Year", and the recipient of the Mortar and Pestle Award. Brooks was a member of the Snyder Memorial Baptist Church in Fayetteville, a director of Fayetteville Academy and former director and treasurer of the Cumberland County Better Health Foundation. He was a past chairman of NC PharmPAC, Director of NC Pharmaceutical Research Foundation, Chairman of the NCPhA Board of Consultants and Chairman of the Institute of Pharmacy.

MILTON STANLEY BURT, Durham, died June 17, 1985 at Hillhaven Convalescent Center. He was 85 years old. He was a graduate of the UNC School of Pharmacy and was first licensed to practice in 1930. He was a member of the Trinity United Methodist Church and the Holly Springs Masonic Lodge. Burt had practiced in several stores in the Durham, Apex, Fuquay-Varina area, and had worked for 28 years at Boone Drug in Durham

DELMER L. TYSINGER, Robbins, died Thursday, February 13, 1986 at his home. He was 38 years old. Tysinger was a graduate of the UNC School of Pharmacy at owner of Seven Lakes Discount Drug Company. He was formerly associated with Tar Heel Drug of Robbins. He had served as President of the Moore County Pharmaceutical Association in 1984.

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As more and more frustrations develop because of problems with third party prescription drug programs, pharmacists are looking to their professional organizations for assistance.

The North Carolina Pharmaceutical Association is leading the formation of a pharmacist-managed Preferred Provider Organization (PPO) to develop and market drug benefit plans in competition with PCS, PAID, Blue Cross, Medimet and others. This PPO, the Carolina Pharmacy Service Network, is currently enrolling pharmacies as charter members, with an initial membership fee of two hundred dollars ($200.00).

What do you get for this money?

First, the satisfaction that at long last, something concrete is being done to help you receive more adequate reimbursement for third party prescriptions. Second, the knowledge that you are in on the ground floor in the formative stages of this corporation development, with the minimum enrollment fee. Third, opportunity for inclusion on the Board of Directors of the CPSN, with the responsibility of making management decisions. Fourth, but not last, a chance to participate in the third party programs marketed by the Carolina Pharmacy Service Network, maybe to an important client in your trading area.

Who is eligible to enroll in the Carolina Pharmacy Service Network?

Any pharmacy in North Carolina may enroll as a charter member of CPSN now. Enrollment fees will increase after the charter enrollment period expires, but that date has not been set. Funds received now will assist with attorney's fees, mailing and record keeping expenses, printing, incorporation costs, travel and meetings and eventually salaries of Network staff.

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YES!! I want to enroll my pharmacy in the Carolina Pharmacy Service Network. I understand this enrollment fee is not a donation or contribution, but a fee to cover the costs of starting up this Network.

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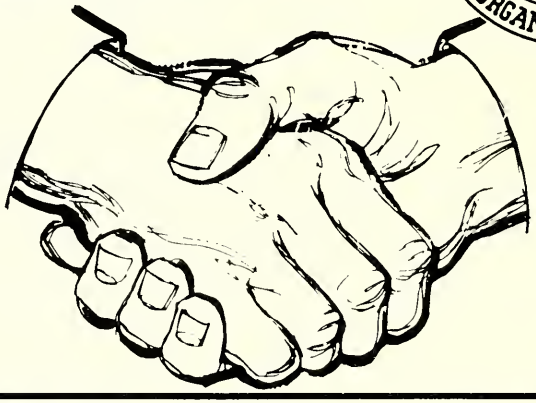

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STAFF PHARMACIST: North Carolina Baptist Hospital, a 701-bed facility affiliated with Bowman Gray School of Medicine, has opening in the Satellite Pharmacy. The pharmacy offers unit dose, nutrition support service, clinical services, and a drug information service. Winston-Salem is located in the Beautiful Piedmont section of North Carolina with beaches and mountains no more than an afternoon's drive. Winston-Salem's cultural attractions include presentations by the North Carolina School of the Arts, Piedmont Chamber Orchestra, Winston-Salem Symphony and NC Dance Theatre. For more information, send resume or call collect: Letha Huffman, NC Baptist Hospital, 300 S. Hawthorne Rd., Winston-Salem NC 27103.

STAFF PHARMACIST: Rutherford Hospital, a progressive 165-bed acute care hospital located in western NC, is seeking a full-time Staff Pharmacist. Unit dose and IV admixture. Excellent salary and benefits. Interested candidates send resume to Personnel Director, Rutherford Hospital, PO Box 889, Rutherfordton NC 28139. (704) 287-7371.

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REYE SYNDROME WARNING

HHS Secretary Otis R. Bowen, M.D., warned that current outbreaks of flu in schools coast-to-coast could result in a major increase in associated cases of Reye syndrome, a rare but serious disease in children and teen-agers.

Dr. Bowen urged parents to familiarize themselves with the symptoms of Reye syndrome — persistent vomiting, belligerent behavior and lethargy progressing to coma — because early hospitalization can be lifesaving.

He and FDA Commissioner Frank E. Young, M.D., also cautioned that children and teen-agers should not be given aspirin for flu without first discussing its possible role in Reye syndrome with a physician. They said FDA is sending a letter to 7,500 radio and TV stations around the country urging them to use previously supplied public service announcements alerting people to a possible link between Reye syndrome and aspirin.

The radio stations were also being supplied new public service announcements to be read on the air regarding the current flu outbreaks and Reye syndrome.

Reye syndrome, which can cause mental retardation or death, usually occurs just when a child or teen-ager appears to be recovering from flu. Some studies have suggested that aspirin's use in flu may increase a youngster's chance of getting Reye syndrome. A major study is underway.

According to the Centers for Disease Control, outbreaks of influenza-like illnesses, particularly among school children, began to be reported in mid-January. In most cases where virus identification studies were undertaken, the virus isolated has been influenza type B, which has been more strongly associated with Reye syndrome than other flu viruses. Reye also is known to follow chicken pox, which occurs mostly in the late winter and spring.

CDC reported Thursday that flu had been reported in 35 states.

FDA's Dr. Young noted that since Aug. 31, 1985, 100 percent of the aspirin produced by major aspirin manufacturers has carried voluntary Reye-related label warnings.

In mid-December 1985, FDA published a proposal to require a consistent Reye syndrome warning statement on aspirin-containing nonprescription products. Comments on the proposal are now under review. Under the proposal, the labeling would go into use and then be reviewed and possibly revised when the Public Health Service completes its full-scale epidemiological study on aspirin and Reye syndrome.

DRUG DIVERSION

(from Rx Ipsa Loquitor, January 1986)

A supervisor-pharmacist for a pharmacy chain in Georgia has been sentenced to six months in jail and a $1000 fine for his illegal drug diversion activities uncovered by a recent Justice Department investigation. The pharmacist was charged with fraudulently obtaining drugs discounted for hospital use which he then resold through his retail pharmacy. In addition, the pharmacist was charged with purchasing manufacturer's samples from sales representatives so that he could remove the original packaging and labeling of those drugs and place in "plastic baggies without accurate lot numbers, expiration dates and other required data" and later sell them in his pharmacy.

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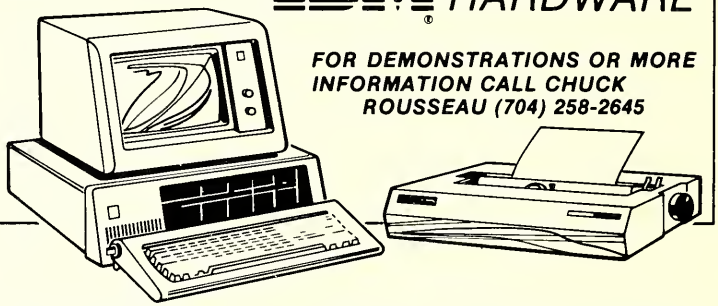

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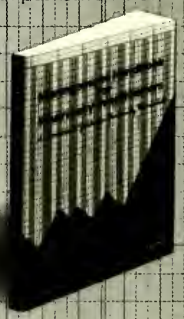

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JEAN PAUL GAGNON RECEIVES AWARD IN ECONOMIC, SOCIAL, AND ADMINISTRATIVE SERVICES

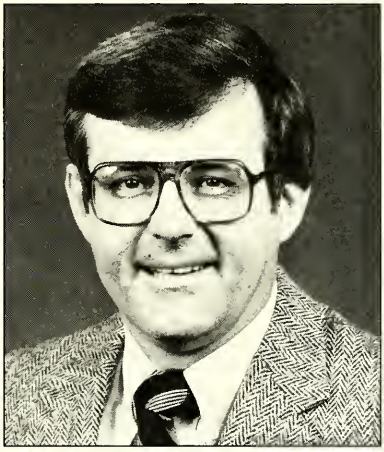
Jean Paul Gagnon, professor and chairman of the division of pharmacy administration at the School of Pharmacy, University of North Carolina at Chapel Hill, has been selected to receive the 1986 American Pharmaceutical Association (APhA) Foundation and APhA Academy of Pharmaceutical Sciences (APS) Research Achievement Award in Economic, Social, and Administrative Sciences at the 1986 APhA Annual Meeting in San Francisco, California, March 16–20, 1986.

The award is presented every two years and is intended to recognize and encourage outstanding and meritorious achievement in the broad areas of administrative and social sciences. Included within the scope of the award are contributions to the administrative, sociological, behavioral, economic, and marketing aspects of drugs and their use in health care.

Gagnon was cited by the selection committee for his studies on pharmacist job satisfaction, pharmacy inventory control, and the impact of federal regulations on pharmacy practice and the U.S. pharmaceutical industry. More specifically, Gagnon was cited "because of his dedicated commitment to using information generated by research to improve the practice of pharmacy and advance the quality of pharmacy practice." The 1986 award will be presented to Gagnon at the APS Awards Ceremony on Monday afternoon, March 17, in San Francisco.

A native of Waterbury, Connecticut, Gagnon received his B.S. in Pharmacy (1963) and his M.S. (1968) from the University of Connecticut. After receiving his Ph.D. in 1971 from Ohio State University, Gagnon joined the faculty at the University of Iowa College of Pharmacy, serving from 1971 to 1975. Since 1975, Gagnon has been on the faculty at the University of North Carolina at Chapel Hill, serving first as associate professor, and commencing in 1979 as full professor of pharmacy administration.

Gagnon served as chairman of the APhA Academy of Pharmaceutical Sciences, Economic, Social, and Administrative Sciences Section 1978–79, and currently serves as president of the American Association of Colleges of Pharmacy. In 1980, his interest in health policy issues led



Jean Gagnon

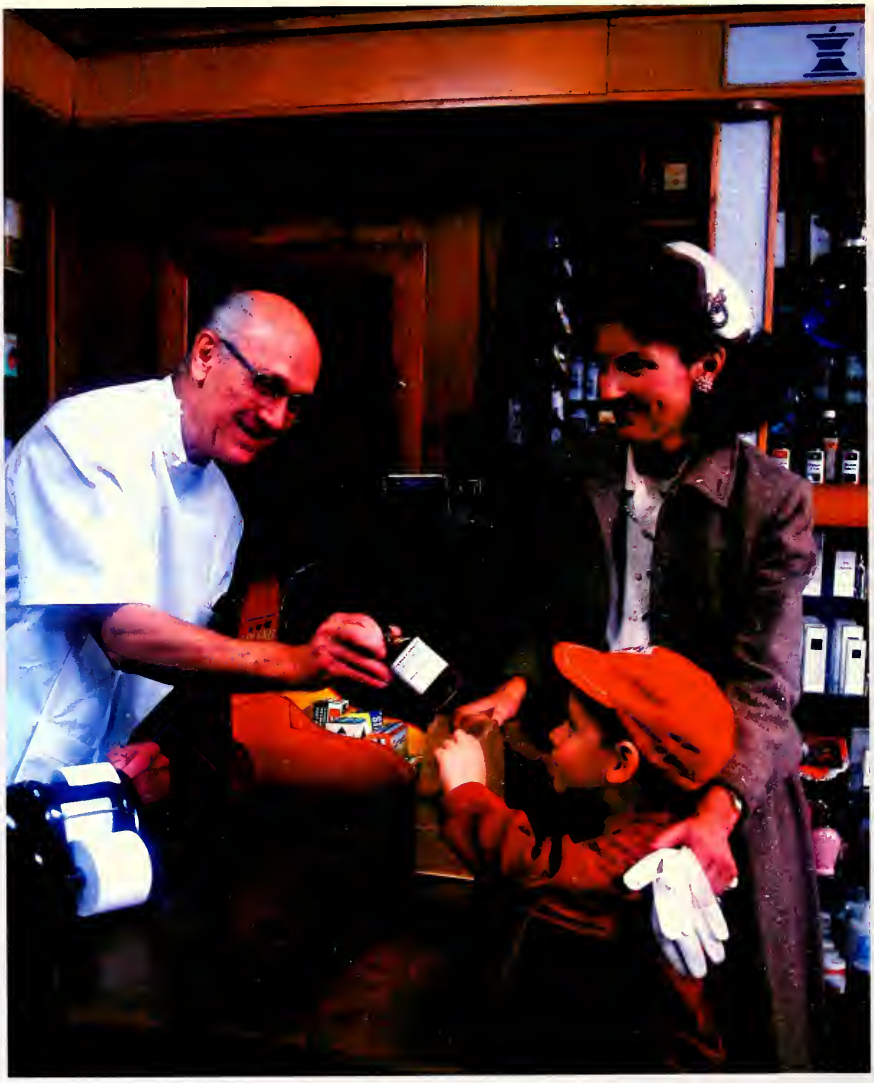
him to apply for a Robert Wood Johnson Health Policy Fellowship, and he was subsequently awarded the fellowship, spending 1981–1982 in Washington, D.C. as a committee staff person on the House Energy and Commerce Subcommittee on Health.

ROCHE REVISES SPELLING OF ANTICONVULSIVE

NUTLEY, N.J., March 6, 1986 — Roche Laboratories, the pharmaceuticals division of Hoffman-La Roche Inc., has revised the spelling of its trade name for the anticonvulsant medication Clonopin® CIV to Klonopin™ (clonazepam/Roche) CIV. The spelling was changed to avoid possible confusion with the generic name clonidine, an antihypertensive product.

In keeping with the company's longstanding commitment to promote efforts to ensure the proper use of all medications, Roche has sent letters to physicians, pharmacists and wholesalers announcing the revised spelling and explaining the reasons for the change. The letters were accompanied by printed aids, including updated complete product information, patient reminder labels to be placed on prescription refills, and physician reminder cards.

While the name change will take effect immediately, any remaining medication imprinted with the previous spelling will continue to be dispensed, since there has been no reformulation of the product.



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RESERVIST STRIVES FOR QUALITY IN FIELD PHARMACY

By Tony Nauroth
Nuernberg bureau

AMBERG, Germany — As a civilian, George Williams is a freelance pharmacist. When the corner drugstore proprietor becomes sick, Williams takes over.

As an Army Reservist, Capt. George Williams has the same sort of job.

The Greenville, N.C., pharmacist is a member of the Individual Ready Reserve in Germany for Reforger (Return of Forces to Germany) and Certain Sentinel. As an IRR soldier, Williams can be plugged into any unit that needs him. He's not assigned to a specific unit — and that suits him fine.

He often serves the Army, not only in his Reserve capacity, but also as a civilian replacement. He calls this assignment in Germany "just another gig on the road."

Williams, 40, presently is on duty with the 128th Combat Support Hospital out of Ludwigsburg. He's dispensing medicines for Certain Sentinel soldiers still serving in the exercise area.

He still retains the strong, lean look of the Green Beret medic he once was. His jump wings still stand out on his Army fatigues.

He often picks jobs that take him to exotic places — jobs that hold special challenges for him.

For example, he worked in Thailand in the Tom Dooley refugee camp hospital along the Laotian border in 1980 when thousands of people were fleeing the "yellow rain" chemical attacks believed to be carried out by Russian aircraft against the Hmong tribe.

"We were short on supplies and actually boiling used hypos (hypodermic needles) so we could use them again," he said.

Such extreme experience has helped mold Williams' philosophy of military medical care and pharmaceutical support.

"My main concern is the hardleg soldier coming out of the field, hurting," Williams said. "Treatment starts with the wound, not with the supplies available for treatment. I'm tired of seeing that wound collide with the supply system.

George Williams

That's a case of the tail wagging the dog.

"If you have 3,000 soldiers arriving with one type of wound requiring a particular drug, and you only have enough to treat three cases, something is wrong."

Williams tried a simple idea during Certain Sentinel that he thinks would greatly reduce supply and handling problems of medicines.

"I stocked all the drugs according to therapeutic classification. They're side by side," he said. "The Army usually stocks them alphabetically by generic name. When you need a replacement for that drug, you've got to go through a long list to find it."

Williams said exercises like Certain Sentinel teach medical personnel what kinds of problems they might face in war or disaster and helps them get a handle on quality control in the field.

"Quality control," he said, "begins with the truth. If we don't face the truth (the kind and quantity of injuries on a real battlefield), then we're not going to have quality."

And quality, he said, means more lives saved.

(Reprinted from *The Stars and Stripes)*

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Northwood Plaza
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10/18/85

SuperX Drugs
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Greensboro, NC (T/O)

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11/4/85

Eckerd Drugs
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Wilson, NC

The Prescription Shoppe
Hwy. 24 & 50
Warsaw, NC

Wilmington Health Associates Phcy.
1202 Medical Ctr. Dr.
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Blackwelder Memorial Hosp. Phcy.
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Lenoir, NC

11/18/85

CPC Cedar Spring Hosp.
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P.O. Box 39
Pineville, NC

Econo Mart Discount Drug Ctr. #4
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Hendersonville, NC

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2700 Wayne Mem. Dr.
Goldsboro, NC (T/O)

11/27/85

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Cherryville, NC (LSP)

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Hill's S/C
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Rite Aid Phcy.
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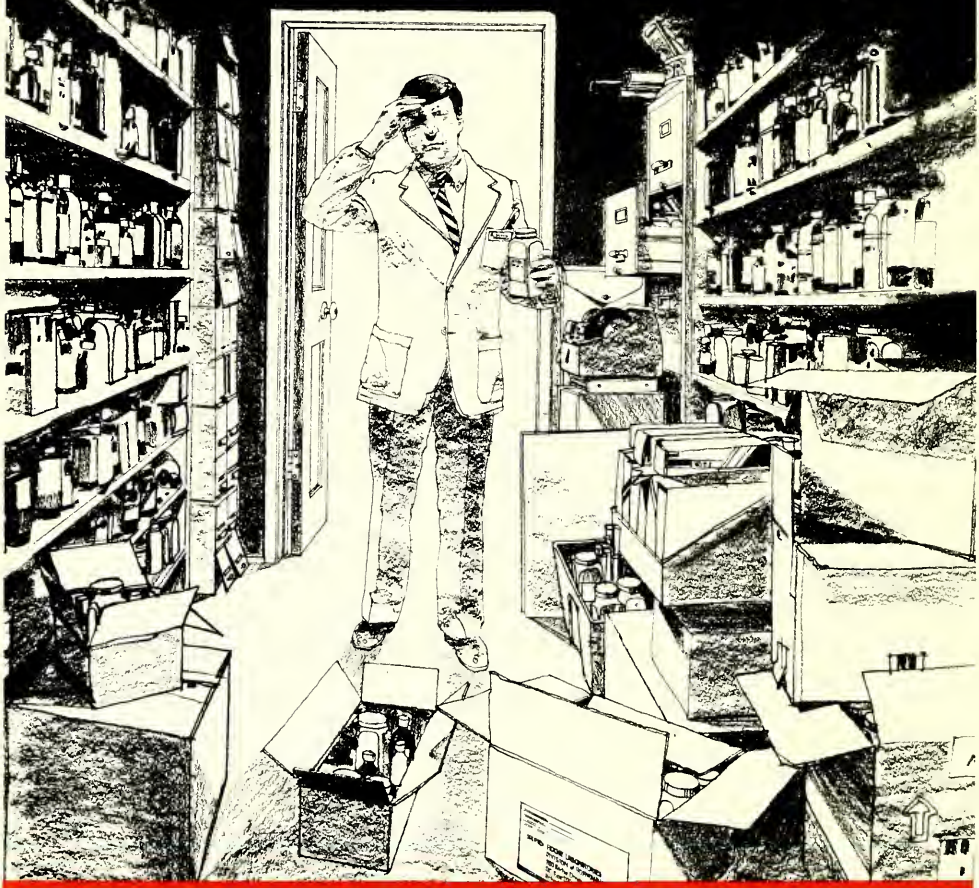

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Pink Hill, NC (T/O)

The Medicine Shoppe
1601 N. Main St.
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1/20/86

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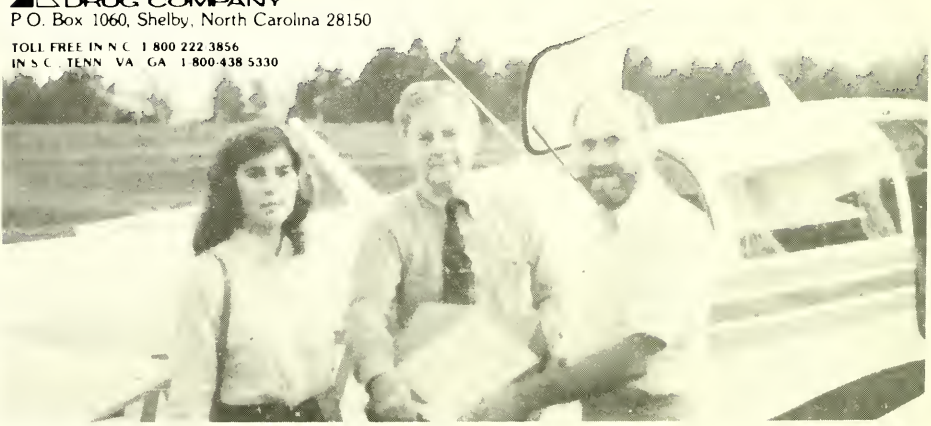

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919-966-1128 & 919-966-1121
PROGRAM CALENDAR

Date	Title	Location	Cosponsors	Contact Person	(*ACPE Approved)
4/4/86	Treatment of Alcoholics	Vance/Granville Comm. Coll., Henderson	4 County Pharm. Association	JB Clay 919-693-7101	2.0
4/6/86	Leading & Motivating Employees	Watauga Co. Hosp. Boone	NW AHEC, High Country Assoc.	Karen Oles 919-748-3967	*2.0
4/8/86	Common Problems & Care of Contact Lenses	Moses Cone Hosp. Greensboro	Greensboro AHEC	Peter Gal 919-379-4025	*2.0
4/8/86	Peptic Ulcer Disease	Pitt Co. Mem. Hosp. Greenville	Eastern AHEC	David Hawkins 919-758-5200	*2.0
4/8/86	Otitis Externa	Kountry Kitchen Res. Wilson	Wilson County Society	Bill Williams 919-237-1121	1.0
4/9/86	Pharmacy Computerization: Is it for You?	Old Hills Rest. Concord	Piedmont Pharm. Society	Nancy Stiles 704-782-1121	2.0
4/10/86	Update on Peptic Ulcer Disease	MAHEC Lect. Hall Asheville	Mountain AHEC	T. Donald Marsh 704-258-0771	*2.0
4/13/86	Anemia Diagnosis & Management	Moses Cone Hosp. Greensboro	Greensboro AHEC Guilford Co. Soc.	Peter Gal 919-379-4025	*2.0
4/16/86	Hypertension	Vance/Granville Comm. Coll., Henderson	4 County Pharm. Association	JB Clay 919-693-7101	3.0
4/20/86	Hypertension Update	Mulls Restaurant Hickory	NW AHEC, Catawba Co. Society	Karen Oles 919-748-3967	*2.0
4/20-4/23/86	NCPhA Convention	Holiday Inn — 4 Seasons Greensboro	NCPhA	Al Mebane 919-967-2237	
4/23/86	6th Annual Management Seminar	Holiday Inn — 4 Seasons Greensboro	NCPhA, School of	Betty Dennis 919-966-1128	*6.0
4/23/86	Management of Drug Addiction	Cutting Board Rest. Burlington	Greensboro AHEC, Alamance Society	Peter Gal 919-379-4025	*2.0
4/23/86	Drug Interactions	Craven Co. Hosp. New Bern	Eastern AHEC	David Hawkins 919-758-5200	*2.0

continued on page 14

4/25- 4/26/86	Drug Therapy/Pharmacy Management	Hotel Radisson High Point	SE Society of Hosp. Pharmacists & School of Pharmacy	Betty Dennis 919-966-1128	*3.0 *7.0
4/29/86	Cardiac Arrhythmias	Albemarle Mem. Hosp. Elizabeth City	Eastern AHEC	David Hawkins 919-758-5200	*2.0
4/30/86	Alcohol & Drug Abuse Among People; A Community Workshop	Adams Community Ctr. Roanoke Rapids	Comm. Alcohol & Drug Educ. Comm.	Betsy C. Williams 919-535-2351	3.0
5/7/86	Common Dermatological Disorders	Pitt Co. Mem. Hosp. Greenville	Eastern AHEC	David Hawkins 919-758-5200	*2.0
5/11/86	Common Problems & Care of Contact Lenses	Moses Cone Hosp. Greensboro	Greensboro AHEC, Guilford Society	Peter Gal 919-379-4025	*2.0
5/13/86	Congestive Heart Failure	Craven County Hosp. New Bern	Eastern AHEC	David Hawkins 919-758-5200	*2.0
5/13/86	Management of Lipid Disorders	Moses Cone Hospital Greensboro	Greensboro AHEC	Peter Gal 919-379-4025	*2.0
5/18/86	Pharmacologic Treatment of Depression & Electroconvulsive Therapy	Eden Public Library Eden	Greensboro AHEC, Rockingham Soc.	Peter Gal 919-379-4025	*2.0
5/18/86	Pediatric Drug Therapy	Bowman Gray Sch. of Med., Winston-Salem	NW AHEC, NW Pharm. Assoc.	Karen Oles 919-748-3967	*2.0
5/20- 5/23/86	Wellness Institute	Mission Valley Inn Raleigh	Wake AHEC	Pam Joyner 919-755-8018	*18.0
5/22/86	Arthritis & Newer Antirheumatic Drugs	MAHEC Lecture Hall Asheville	Mountain AHEC	T. Donald Marsh 704-258-0881	*2.0
5/28/86	Gout & Hyperuricemia	Albemarle Mem. Hosp. Elizabeth City	Eastern AHEC	David Hawkins 919-758-5200	*2.0
5/28/86	Pharmacologic Treatment of Depression & Electroconvulsive Therapy	Cutting Board Rest. Burlington	Greensboro AHEC & Alamance Co. Society	Peter Gal 919-379-4025	*2.0
6/12/86	Update on Antihypertensive Therapy: Step Care — R.I.P.	MAHEC Lecture Hall Asheville	Mountain AHEC	T. Donald Marsh 704-258-0881	*2.0
6/15- 6/19/86	20th National Medicinal Chemistry Symposium	Paul Green Theatre UNC, Chapel Hill	UNC School of Pharmacy	George Cocolas 919-962-0098	TBA
6/20/86	Making Change & Conflict Work for You	Inn on the Plaza Asheville	NCSHP, UNC School of Pharmacy	Betty Dennis 919-966-1128	*6.0
7/13/86	Substance Abuse	Bowman Gray School of Med., Winston-Salem	NW AHEC, NW Pharm. Soc.	Karen Oles 919-748-3967	*2.0
7/20/86	Pediatric Drug Therapy	Mulls Restaurant Hickory	NW AHEC, Catawba County Society	Karen Oles 919-748-3967	*2.0
7/20/86	Pharmacologic Treatment of Manic Depression	Eden Public Library Eden	Greensboro AHEC, & Rockingbam Soc.	Peter Gal 919-379-4025	*2.0

8/3- 8/7/86	CE Institute	Hotel Europa Chapel Hill	UNC School of Pharmacy	Betty Dennis 919-966-1128	TBA
9/2/86	Drug Effects in the Fetus and Newborn	Wilmington AHEC Wilmington	Wilmington AHEC	Bruce Canaday 919-343-0161	*2.0
9/9/86	Pediatric Cough & Cold	Wilmington AHEC Wilmington	Wilmington AHEC	Bruce Canaday 919-343-0161	*2.0
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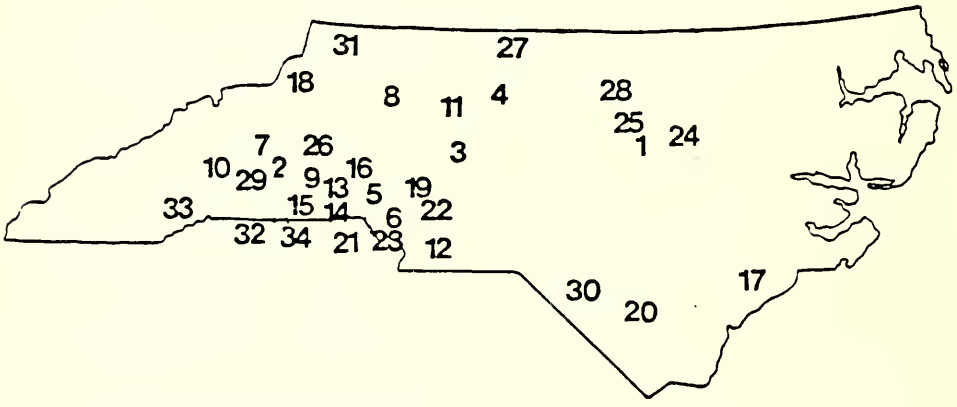

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CORRESPONDENCE COURSE
ADVISING CONSUMERS ON OTC ORAL HEALTH CARE PRODUCTS

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati, Cincinnati, OH
and
Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
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GOALS

The goals of this lesson are to:
1. discuss the pharmacology of drugs used to treat minor oral health disorders;
2. explain how to advise patients on their use.

OBJECTIVES

At the completion of this lesson, the successful participant will be able to:
1. recognize safe and effective OTC agents for treating minor mouth disorders;
2. identify the pharmacologic action of these agents;
3. explain the proper technique for applying these products.

This is the second lesson in a three-part series on OTC remedies for oral discomfort and health. In the first article, the agents used for relief of oral discomfort were discussed. You may want to refer to the *Glossary of Oral Health Care Terms* included in that article.

This lesson will review drugs used for oral health care. They include the analgesic/anesthetics, antimicrobial agents, astringents, debriding agents, decongestants, demulcents, and expectorants.

Although there are some similarities among the drugs covered in these two lessons, the two categories of ingredients were reviewed separately by the FDA OTC panel.

ORAL BACTERIA

Bacteria surround us in our environment. Some of them reside in the alimentary canal. These are involved in many beneficial functions including digestion, vitamin production, and maintenance of a healthy flora. Nonpathogenic organisms have free entry into and out of the mouth, nasopharynx, and throat. They help prevent their pathogenic cousins from gaining a foothold there and overgrowing to cause disease.

The mouth possesses several physiological mechanisms to maintain a proper balance of bacteria and, therefore, a healthy state. It does this without mouthwashes, gargles, or the various "twice a day — once for me and once for you" products so frequently seen in television advertising. Those that do not contain therapeutically active ingredients are considered by FDA to be cosmetics rather than drugs. As long as their manufacturers do not make specific drug-related claims, the cosmetic products are not subject to the regulations explained in this lesson.

Many different glands moisten and clean the mouth's mucous membranes and teeth, and possibly inhibit excessive bacterial growth. These include the salivary, mucous (secreting viscous materials), and serous (secreting thin, watery fluids) glands.

There is little evidence to prove that oral health care products prevent the development of any disease, or maintain a "healthy" state in

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in the service of pharmacy

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OTC Oral Health

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otherwise well persons. However, in the presence of fever, and as a result of the atropine-like side effects of some drugs, oral secretions can be decreased, organic material may accumulate and decompose, and bacteria can overgrow. Inflammations, ulcerations, sore throat, mouth discomfort and pain, and foul breath can result and may require some type of oral health care product.

PAIN RECEPTORS

Oral mucous membranes contain sensory receptors for cold, pain, pressure, touch, warmth, and in the tongue, specialized receptors for taste. Pain receptors will be emphasized in this article because oral discomfort and pain can be effectively alleviated by topical analgesics and anesthetics. For example, local anesthetics readily penetrate the mucous membranes of the mouth and inhibit the passage of pain impulses to the brain.

While systemic analgesics will not be discussed in this lesson, it should be kept in mind that oral pain can also be relieved by raising the pain threshold or altering the psychological response to it. Aspirin and acetaminophen can be recommended for temporary relief of minor irritations, pain, sore throat and sore mouth. Either analgesic may be just as effective, or more effective in some patients, as the topical anesthetics.

Sore throat may be described as burning, discomfort or pain, or as a "scratchy" feeling, especially when swallowing. It is considered to be self-treatable if it results from a common cold, minor irritation or trauma. However, lingering persistent, or severe sore throat can also signal a more serious disease state. Diseases for which sore throat is a symptom are listed in Table 1.

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TABLE 1
Representative Diseases for Which Sore Throat is a Symptom

Agranulocytosis
Aplastic anemia
Cancer
Caustic chemical poisoning
Chicken pox
Diphtheria
Foreign substance reactions
Influenza
Leukemia
Measles
Moniliasis (Thrush)
Oral gonorrhea
Pneumonia
Poliomyelitis
Rheumatic fever
Scarlet fever
Smallpox
Syphilis
Tonsillitis
Vincent's agina

When the regulation is finalized, the following warning statement will be required to appear on all OTC oral health care products:

Severe or persistent sore throat or sore throat accompanied by fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor. Discontinue use and consult a doctor if irritation persists or increases or a rash appears on the skin.

Sore mouth may also be a symptom of some other disorder. There are many causes of sore mouth including burns, cancer, infections, metabolic disorders, systemic disease, and trauma — especially from improperly fitted dentures. As with sore throat, only a very few causes are self-treatable. Also, the mouth has its own efficient mechanisms for healing minor sores without the aid of OTC products.

Nonetheless, oral health care products do play a beneficial role in alleviating pain of mild, benign, short-lived mouth sores. Local anesthetics (and systemic analgesics) can alleviate mouth pain or discomfort, and debriding agents can facilitate removal of exudate and debris from mouth sores. Astringents and demulcents can relieve discomfort, or form a protective covering over mouth sores preventing entry of irritating substances. These agents will now be discussed.

ANESTHETICS/ANALGESICS

Anesthetics/analgesics for oral health care are categorized into two groups: the "caine-type" anesthetics and the alcohol or hydroxyl compounds. The "caine-type" anesthetics penetrate into the oral mucosal membranes and block the pain receptors. The alcohol or hydroxyl compounds have various actions, one of which is to stimulate receptors other than those for pain — most specifically, the cold receptors. These agents may also depress the nerves or merely substitute the sensation of cold for pain.

In either instance, when an agent blocks the perception of pain only, it is officially referred to as an **analgesic.** When a drug also blocks cold, pressure, touch, and warmth (thereby inducing numbness), it is called an **anesthetic.** Since most of the agents that are effective in alleviating oral pain and discomfort produce both of these actions, depending on their concentrations, within the epithelial tissue, we will refer to them from this point forward simply as local anesthetics.

It is hypothesized that the "caine-type" anesthetics change the pore size of neurons and, therefore, distort the channels for passage of sodium ions into the axon. This stabilizes the membrane of the nerve fiber in such a way that impulses generated cannot pass by and gain entry into the CNS. This action is reversible and dissipates as the anesthetic is metabolized and carried away from its site of local application.

Another agent that does not fall into either of the above groups is aspirin. Aspirin has elicited controvery within the OTC advisory panels. The panel reviewing fever blister remedies concluded that aspirin may cause ulceration of the oral mucosa, and, therefore, should not be applied topically to the mouth. The panel reviewing OTC systemic analgesics stated that aspirin in chewing gum formulations may irritate and damage oral mucosa, and may be unsafe if the tissue is highly inflamed or abraded. That panel concluded that the topical use of aspirin for sore throat has not been adequately tested, and deferred all decisions to the Advisory Panel on OTC Oral Health Care Drugs.

The majority of the latter panel ruled that aspirin is a safe and effective analgesic for topical use on mucous membranes of the mouth and throat when used properly. The word *majority* is mentioned because several of the panel's

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members issued a *minority* report. The opinion of the minority was that aspirin does not exert a topical anesthetic effect, does not block transmission of nerve impulses, and, therefore, has no known anesthetic action on mucous membranes. These panel members further stated that gargling with aspirin solution produces irritation and burning instead of a numbness effect. It was the consensus of the minority that the topical use of aspirin in *any* form is unwarranted and unjustified, especially since safer and more effective agents are available.

The majority and, therefore, the official monograph opinion was that aspirin is unsafe for topical application to the oral mucosa after oral surgery, when the mucous membranes are highly inflamed or abraded, when there are ulcerations present, or when the person is taking oral anticoagulants. Otherwise the panel believed it to be safe and effective. It concluded that aspirin has a local analgesic action both from a peripheral effect and a systemic effect from absorbed aspirin. The proposed mechanism of action is that it blocks the chemoreceptors that mediate pain and inhibits prostaglandin synthesis. This reduces inflammation and removes one of the causes of pain. The majority view was that 130 to 500 mg of aspirin incorporated in a chewing gum base, to be chewed every four hours when needed, is safe and effective for OTC marketing. The panel recommended that several warnings appear on the labels of aspirin used for oral health related care. These are listed in Table 2.

Benzocain and **dyclonine** are two members of the "caine-type" local anesthetics that have been used for years for treating all types of topical pain. The panel approved benzocaine in a 5 to 20% gel or spray, and in a 0.05 to 0.1% strength for lozenge formulation. Dyclonine was accepted in concentrations of 0.05 to 0.1% for rinse, gargle, spray and lozenge dosage forms.

Representatives of the alcohol/hydroxyl-type topical anesthetics and concentrations that were approved are: **benzyl alcohol,** 0.05 to 0.1%; **menthol,** 0.04 to 2%; and **salicyl alcohol,** 1 to 6%. Phenol, its sodium salt, and its derivative hexylresorcinol were also accepted. The respective strengths are 0.5 to 1.5% for **phenol** and **phenolate sodium,** and 0.05 to 0.1% for **hexylresorcinol.** Available dosage forms include gargles, mouthwashes, rinses, sprays and lozenges.

TABLE 2
Suggested Warnings for Labeling of Oral Health Care Analgesics Containing Aspirin*

- Do not use if you are sensitive or allergic to aspirin.
- Do not use if you have a bleeding problem or if you are taking an anticoagulant drug.
- Do not use without a physician's or dentist's advice, if your mouth is highly irritated or ulcerated.
- Do not use after surgery on the mouth or throat.
- Provide good fluid intake when aspirin or aspirin-containing preparations are used.

*as determined by an FDA advisory panel

Camphor and **cresol** were ruled to be neither safe nor effective because of lack of supporting evidence. Also, reports show that they may excessively irritate mucous membranes and are possibly absorbed in sufficient quantities to cause systemic effects. **Dibucaine, lidocaine,** and **tetracaine** were tabbed as effective, but unsafe for oral use. In the panel's opinion, they can be absorbed in sufficient quantities to be systemically toxic.

Eucalyptol, methyl salicylate and **thymol** were placed in the "needs more study" category. Even though they have characteristic "medicinal" odors, evidence that they actually exert a pharmacologically significant anesthetic effect on the oral mucosa is lacking. Other panels have also rejected their uses except as flavoring agents.

ANTIMICROBIALS

The antimicrobials have several mechanisms of action. Alcohol, phenol and salts of aluminum, mercury and zinc coagulate or denature protein within the protoplasm of susceptible organisms, and kill them. Surfactants such as the quaternary ammonium compounds affect the membrane surface tension of susceptible organisms and allow the escape of cellular content. The exact mechanism for this action is unknown, but it is thought to result from a combination of any of the following: disrupting of the cell membrane, dissolving the protective lipid film around the organism, denaturing cellular protein in the membrane, inactivating certain enzymes within

the cell, or interfering with enzyme systems in the transport mechanism across cell membranes. Still other antimicrobials (e.g., hydrogen peroxide, carbamide peroxide) exert their mechanism of action by oxidizing and killing organisms.

A great deal of controversy surrounds the use of "antiseptic" solutions in the mouth. Some hold that the dynamic nature of a contaminated wound overwhelms the action of antiseptics and renders them useless. Others feel that antiseptics harm both microorganisms and human cells, and that the risks outweight the benefits. More importantly, the introduction of antibiotics and chemotherapeutic agents specific for these organisms, without harming human cells, should have relegated antimicrobials such as boric acid and camphor into oblivion. Those who advocate the removal of antimicrobials for oral health care have listed their reasons in Table 3.

In spite of the above opinions, the general public and even health professionals are still convinced that the topical use of antiseptics will relieve symptoms of infection and accelerate healing. Documentation that these agents actually exert a beneficial antimicrobial action is lacking.

TABLE 3
Proposed Reasons Why Antimicrobials Are Not Appropriate for OTC Oral Health Care Use*

- Consumers cannot identify causative organisms
- Consumers cannot determine agent of choice
- Action is too superficial and does not penetrate down to the deep-seated organisms
- Nonpathogenic organisms are killed, therefore disturbing normal flora and possibly allowing overgrowth of pathogens
- Rapidly diluted and carried off by saliva and other secretions
- Resistant strains may develop
- Nullify the action of immune systems in the mouth
- No clinical trials have demonstrated that antimicrobials are safe or effective for this use
- Toxicity studies on long-term use are not available

*as determined by an FDA advisory panel

IS BAD BREATH A DISEASE?

Current scientific thinking is that oral malodor is normal. It is not a disease. Mouth odor occurs sometime in nearly everyone; a study has shown that 9 out of 10 persons have what they, or someone else, considers to be bad breath. Bad breath itself has little, if any, correlation to systemic or oral disease. There is no need to self-treat mouth odor with medicated products.

Bad breath is common in the morning upon arising. During sleep, the tongue, cheeks, and mouth are at rest. Salivary secretion is minimal and bacteria normally in the mouth are active and forming volatile sulfur compounds which may cause mouth odor.

The lay public is convinced that "correcting" oral malodor is necessary. Therefore, breath-freshening products constitute big business. A review of how mouth odors can be eliminated is in order.

There are four methods to effectively eliminate mouth odors. **Purging** can be accomplished by rinsing the mouth with water (or a mouthwash), brushing the teeth (a more effective means), using dental floss, or eating high fiber food. **Masking** is the second method. As the name implies, this consists of replacing the natural odor of the mouth with a more pleasant one from a mouthwash or other means. Chemical **neutralization** of the volatile materials in the mouth is the third method.

Since the odor results from bacterial metabolic reactions, the fourth and most effective method for eliminating bad breath is via **bacterial inhibition.** Even so, the FDA advisory panel's report states that, to be truly effective, antimicrobial agents would need to be used daily every three to four hours. It does not consider this to be a "judicious" practice, and does not recommend unsupervised used of antimicrobial agents, especially when there are no symptoms and no disease.

SAFE AND EFFECTIVE OTC ANTIMICROBIALS FOR ORAL HEALTH CARE

After reviewing all of the available data, the panel could not find sufficient evidence to

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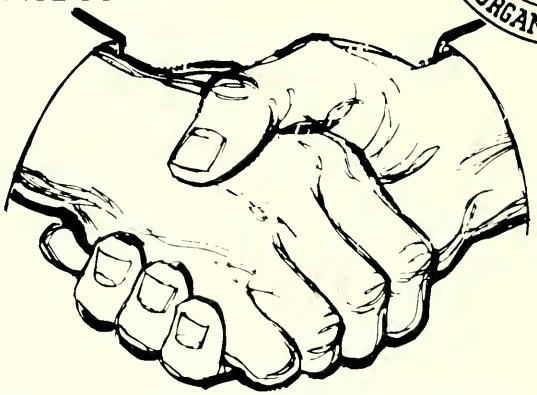

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OTC Oral Health

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conclude that any antimicrobial should be given the "safe and effective" classification. It found quite a few "needs more study" substances which are listed in Table 4. These agents can be subdivided into several categories: the quaternary ammonium compounds (e.g., benzalkonium chloride), the volatile oils (e.g., eucalyptol), phenol derivatives, oxidizing agents (e.g., hydrogen peroxide), and miscellaneous substances (e.g., alcohol, gentian violet, povidone-iodine).

The **quaternary ammonium compounds (QAC's)** are undoubtedly safe, but evidence of effectiveness is lacking. The proteins, neutralizing chemicals, organic materials and bacterial by-products in the mouth overwhelm the antimicrobial action that QAC's exert when they interact with bacteria in a test tube.

The same holds true for the **volatile oil ingredients** such as **eucalyptol, menthol, methyl salicylate** and **thymol.**

Oxidizing agents include **carbamide peroxide** and its active principle, hydrogen peroxide. **Hydrogen peroxide,** when acted on by several enzymes (catalase most importantly), decomposes into oxygen which can kill microorganisms before it is transformed into elemental oxygen which then bubbles up. This debriding action helps clear debris out of ulcers and wounds. However, it has also been found that most bacteria are partially or completely resistant to the germicidal action of peroxides. Their effectiveness as antimicrobials is now being questioned.

Although **chlorophyll** is a popular ingredient in "breath mints," evidence that it is an effective antimicrobial does not exist. We do know that chlorophyll is safe and it is green.

Ethyl alcohol is known to kill microorganisms by denaturing and precipitating their proteins. However, the only studies conducted to date involve concentrations that are too irritating to oral ulcerations or inflamed mucous membranes for antiseptic use.

Gentian violet, long used as an antibacterial, anthelmintic and antifungal agent, has been replaced by newer, more effective, and nonstaining agents. It is still considered to be an effective agent for treating candidal infections (e.g., thrush) in the mouth, but the diagnosis and treatment of thrush requires physician intervention.

Iodine is considerd to be one of the most potent antimicrobials known. **Povidone-iodine** reportedly acts by slowly releasing iodine, thus reducing its toxicity potential. The problem with iodine itself is that it may actually injure tissue and delay wound healing. **Phenol** has similar actions.

TABLE 4
Antimicrobials for Oral Health Care*

A. Proven Safe and Effective: None

B. Safe But Insufficient Evidence to Prove Effectiveness:

Benzalkonium Cl	Iodine
Benzethonium Cl	Menthol
Benzoic acid	Methyl salicylate
Carbamide peroxide	Oxyquinolin SO_s
Cetalkonium Cl	Phenol
Cetylpyridinium Cl	Phenolate sodium
Chlorophyl	Povidone-iodine
Dequalinium Cl	Secondary amyltricresols
Domiphen Br	Sodium caprylate
Ethyl alcohol	Thymol
Eucalyptol	Thymol iodide
Gentian violet	Tolu balsam
Hydrogen peroxide	

C Unsafe and/or Ineffective

Boric Acid	Meralein sodium
Boroglycerin	Nitromersol
Camphor	Potassium chloride
Cresol	Sodium dichromate
Ferric chloride	Tincture of myrrh

*as published by FDA, 5/82

The FDA panel feels that the above products, and the others listed in Table 4, have some, but inconclusive, evidence that they are effective. The panel has given manufacturers protocols to follow and time to prove the effectiveness of these ingredients. If manufacturers are not able to prove this, they will not be permitted to promote them for oral antisepsis.

Other agents such as **boric acid, camphor** and **mercury-containing compounds** have been ruled to be unsafe and ineffective for use as antimicrobial oral health care products (see Table 4).

Both the American Academy of Pediatics and the FDA Advisory Panel on OTC Oral Health Care Drugs condemn the topical use of boric

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OTC Oral Health

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acid. In 1962, 172 cases of boric acid intoxication occurred resulting in 89 deaths. In 53 of these cases, the boric acid was applied topically for diaper rash and 23 infants died.

ASTRINGENTS

Astringents precipitate proteins in living cells of mucous membranes, and form a protective film on the surface of the cells. This reduces the sensitivity of receptors to external stimulation. While the permeability of the cell membrane is decreased, the cell itself remains viable and there is no permanent injury to it.

In oral health care, astringents are used as "protective" coatings on irritated, inflamed, ulcerated, or abraded tissues. When effective, astringents will relieve pain and discomfort by this protective activity. They are not analgesics because astringents have no action on pain receptors.

Astringents found to be safe and effective by the OTC advisory panel are **alum** (ammonium, potassium, or sodium aluminum sulfate) and **zinc chloride.** Potassium aluminum sulfate is the most common of the three alum forms used in medicine. In fact, its synonym is medicinal alum (also kalinite). Alum in a 0.2 to 0.5% solution provides a protein precipitating astringent activity with no corrosive effect on the mucous membranes. It is considered to be a safe and effective astringent that aids in the relief of sore mouth or sore throat. This action is symptomatic; alum does not have curative effects.

A 0.1 to 0.25% aqueous solution of zinc chloride is also a safe and effective astringent. Current theory is that the zinc ion provides the astringent action by precipitating proteins. It has the same indications as alum.

DEBRIDING AGENTS

These are substances that soften, loosen, and remove exudates, mucus, and other secretions

CONGRATULATIONS TO

TRIP MAY

On remodeling May Pharmacy in Burlington. It was our pleasure and privilege to assist in this project.

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from the surface of lesions in the mouth and throat.

Two types have been proven to be safe and effective: the **peroxides** (hydrogen peroxide and carbamide peroxide), and **sodium bicarbonate.** The peroxides act as debriding agents by mechanically removing debris from tissue with which they come in contact.

Carbamide peroxide is comprised of urea and hydrogen peroxide in an anhydrous solution of glycerin. When it comes into contact with water, air or light, it slowly decomposes into its components. While it has a somewhat longer duration of action, both it and hydrogen peroxide exert the same actions.

When **hydrogen peroxide** comes in contact with tissues, it is converted into water and nascent oxygen which is claimed but not yet proven to be an antimicrobial. It is, however, an effective debriding agent. As elemental oxygen is formed, it bubbles up and loosens debris, mucus, pus and other materials present in wounds or ulcerations. It has very little action on intact skin or mucous membranes.

Sodium bicarbonate exerts its debriding action by mechanically washing substances off the surface of mucous membranes. It has a mucolytic action and disintegrates mucus by separating the protein in the mouth from polysaccharides which hold mucus together. Sodium bicarbonate also combines with tissue protein to form sodium albuminate (soap) that softens and soothes epithelial tissue.

When used in the mouth or throat in a 5 to 10% solution, sodium bicarbonate loosens and softens mucus, thus facilitating expectoration. Its debriding action aids in the relief of pain and discomfort of sore mouth and throat.

Another peroxide product that has been used for years, but which this panel found to be unsafe and ineffective for OTC use as a debriding agent, is **sodium perborate (Vincent's solution).** The panel considered it to be unsafe because it is a boron derivative. When absorbed, it may be as toxid as boric acid. The panel concluded that it is ineffective because the quantity of oxygen released when sodium perborate is applied to tissue is insufficient to act mechanically as a debriding agent.

However, the status of sodium perborate is questionable at this time. In response to a similar finding by a panel that reviewed oral wound cleansers, FDA has countermanded the placing of sodium perborate in the "unsafe and ineffective" category.

On reviewing the comments and the additional data submitted after that panel's report, FDA concluded that sodium perborate was safe and effective for OTC use as an oral wound cleanser. The same potential exists for its use as a debriding agent.

DEMULCENTS

Demulcents are substances that form viscous solutions in water and a cohesive protectant film on the surface of tissues to which they are applied. Pharmacologically they are inert and do not react with tissue. Nonetheless, they are considered to be drugs because they prevent access of irritating and sensitizing substances to inflamed or ulcerated tissue.

Many different substances exert demulcent activity including natural gums, mucilages, starches, polysaccharides, colloidal materials, and other high molecular weight polymers. Those stated to be safe and effective for OTC oral health care use are gelatin, glycerin, pectin, and elm bark.

Gelatin is a protein material obtained from collagen by-products of animal origin, or made synthetically. Although it is digestible, it does provide a protective coating over irritated or ulcerated areas in the mouth and throat. It is most commonly used in lozenges for this purpose.

Glycerin mixed in 2 to 3 parts water is also an effective demulcent. It coats mucous membranes with a thin adherent film, thus providing a protective coating. Higher strengths should not be used because they can cause a burning sensation which is irritating but not dangerous.

Pectin is also a protectant. When mixed with water, it forms a suspension of highly hydrated particles which cling to and form a cohesive film on irritated, inflamed, or ulcerated mucous membranes.

"Slippery" elm bark was used for medicinal purposes long before the FDA was established. It comes somewhat of a surprise that a group of scientists has been able to prove that an "old time" home remedy is indeed a safe and effective drug.

The panel found enough data to rule that 10 to 15% ground elm bark, formulated with gums or agar as lozenges, yielded a mucilage when placed in the mouth. This mucilage forms a protective barrier over irritated and inflamed mucous membranes.

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OTC Oral Health

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TABLE 5
Safe and Effective OTC Oral Health Care Products*

1) Anesthetics/ analgesics	Indication
Aspirin Benzocaine Benzyl alcohol Dyclonine HCl Hexylresorcinol Menthol Phenol Phenolate sodium Salicyl alcohol	For the temporary relief of occasional minor irritation, pain, sore mouth and sore throat
2) Astingents	**Indication**
Alum Zinc chloride	Aids in temporary relief of occasional minor irritation, pain, sore mouth and sore throat
3) Debriding Agents	**Indication**
Carbamide peroxide Hydrogen peroxide Sodium bicarbonate	Aids in removal of phlegm, mucus, or other secretins in the temporary relief of discomfort due to occasional sore throat or sore mouth
4) Demulcents	**Indication**
Elm Bark Gelatin Glycerin Pectin	Aids in temporary relief of minor discomfort and protects irritated areas in sore throat and sore mouth

*conclusions of an FDA advisory panel

Decongestants and **expectorants** are two categories of agents that are claimed to be effective in oral health care, but they have not yet been proven.

Both phenylephrine and phenylpropanolamine are sympathomimetic decongestants. They have been sold in this country in lozenge form for the relief of sore throat. Phenylpropanolamine relieves nasal congestion when taken orally and phenylephrine when applied topically. But there is still no evidence that they produce any direct beneficial effect by topical application on sore throats.

Certain **expectorants**, i.e., ammonium chloride, horehound, and tolu balsam, are also promoted for relief of sore throat. As a group, the expectorants have not (with the exception of guaifenesin in higher than previously recommended doses) been proven to be of any greater benefit for relieving cough than drinking lots of fluids. The panel concluded that the use of expectorants is based on tradition, hearsay, and empirical impressions rather than scientific fact.

The above agents have not been shown to be effective in alleviating sore throat. Table 5 represents a summary of currently safe and effective oral health care products.

CE TEST ON PAGE 30

OTC INDUSTRY POSTS REWARD; OPENS HOTLINE TO PUBLIC

The U.S. nonprescription, over-the-counter (OTC) medicines industry today offered rewards totaling $700,000 for information leading to the arrest and conviction of any person or persons responsible for a series of criminal tamperings with OTC medicines dating back to 1982. The amount is in addition to $100,000 previously offered by Johnson & Johnson in each of two cases involving their Tylenol product and brings the total rewards now being offered to $900,000.

Speaking for the industry, James D. Cope, president of The Proprietary Association (PA), said that a telephone hotline has been set up for people who may have information about the crimes. The number is 1-800-222-3081 and the line will be open day and night, beginning immediately.

The tamperings for which the reward is posted began in the Chicago area in September 1982, when seven persons died from cyanide poison in Tylenol Extra-Strength Capsules.

The second case was reported in February 1986 in Westchester County, New York, and one person died. Again Tylenol was poisoned with cyanide.

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LOCAL NEWS

CHARLOTTE WOMAN'S PHARMACEUTICAL AUXILIARY HOLD ANNUAL "FUN DAY" LUNCHEON

The Charlotte Woman's Pharmaceutical Auxiliary had its annual "Fun Day" luncheon, Tuesday, March 11, 1986 at the Idlewild Country Club. Music was furnished by guitarist Gene Ammons.

Plans were under the direction of Betty (Mrs. Don) Smith, chairman, assisted by Georgia (Mrs. Robert) Lewis, Marguerite (Mrs. Johnie) Bennick, Jewell (Mrs. Jesse) Oxendine, and Mary Lou (Mrs. Leslie) Davis. A St. Patrick's Day theme was carried out in the attractive decorations. Mrs. Lewis gave the devotional.

Special guests were Jean (Mrs. Lamar, Jr.) Morse of Raleigh, the state auxiliary president, and Peggy (Mrs. Jimmy) Jackson, state auxiliary corresponding secretary. Mrs. Morse expressed her appreciation to the auxiliary for its support of the state projects and gave plans for the State convention.

Mrs. Oxendine gave numerous door prizes to the holders of lucky numbers and presented gifts to our two special guests.

Virginia Steele, (Mrs. T.K.)

BLANCHARD ELECTED TO BOARD OF DIRECTORS OF UNITED FEDERAL SAVINGS AND LOAN ASSOCIATION

The election of Norwood P. Blanchard from Burgaw, North Carolina to the Board of Directors of United Federal Savings and Loan Association was announced by J. O. Clifton, Jr., President and Chief Executive Officer. Mr. Clifton stated that Mr. Blanchard would be a valuable addition to the Board with his educational foundation, prior financial background with a banking institution and his current business associations.

Mr. Blanchard is owner and President of Discount Drug Center, Inc. He also serves as Project Owner of Farmers Home Administration Apartments in Burgaw, North Carolina. Mr. Blanchard is presently Chairman and member of the Pender County Health Department, Vice President of the Burgaw Rotary Club, member of the North Carolina Pharmaceutical Association and the North Carolina Rental Housing Council.

The Northeastern Pharmaceutical Association met Wednesday February 12, 1986 at 7 PM at Cobb's Restaurant in Williamston.

There were 47 members and 4 special guest present. The special guest included: Mr. Bill O'Quinn, N.C. Mutual Who. Drug, Mr. Mike Langston, Bristol Labs., Ms. Penny Hennison, Hoeschst-Roussel Labs, Mr. David Hawkins of Eastern AHEC.

Mr. Hawkins gave an informative program on Type II diabetes and oral hypoglycemic agents. It is always a pleasure to have Mr. Hawkins as our guest speaker.

President Bill Brown presided over the meeting: Topics also discussed were fees received by various third party programs.

Michael Adams Sec. Treasurer

KAPPA EPSILON FRATERNITY TO MEET

The North Carolina Alumni Chapter of KAPPA EPSILON FRATERNITY will meet Sunday, April 27, 1986 at 2:00 pm in Raleigh. This will be a busy meeting since we will be considering changes in the Bylaws and electing new officers. Anyone interested is welcome to attend. For more information, call (919) 781-2060.

CORRESPONDENCE COURSE QUIZ

Oral Health Care

1. Local anesthetics block the movement of nerve impulses through the area to which they are applied by interfering with the passage of which of the following ions into nerve fiber cells?
   a. Calcium
   b. Magnesium
   c. Potassium
   d. Sodium
2. The FDA Advisory Panel on Oral Health Care Drugs has concluded that the use of boric acid as an OTC oral antimicrobial agent is:
   a. both safe and effective.
   b. effective but of questionable safety.
   c. neither safe nor effective.
   d. safe but of questionable effectiveness.
3. The panel also concluded that the use of aspirin chewing gum for the temporary relief of occasional minor irritation of the mouth is:
   a. both safe and effective.
   b. effective but of questionable safety.
   c. neither safe nor effective.
   d. safe but of questionable effectiveness.
4. The panel further concluded that the use of camphor spirits to treat minor oral pain is:
   a. both safe and effective.
   b. effective but of questionable safety.
   c. neither safe nor effective.
   d. safe but of questionable effectiveness.
5. The panel concluded that which of the following is a safe and effective anesthetic for treating oral mucosal pain?
   a. Dibucaine
   b. Dyclonine
   c. Lidocaine
   d. Tetracaine
6. Elm bark, when formulated in a lozenge dosage form, has been concluded as being a safe and effective:
   a. anesthetic.
   b. demulcent.
   c. astringent.
   d. debriding agent.
7. Because this may be a symptom of a serious systemic disorder, OTC oral health care products must bear a warning concerning their use to treat persistent:
   a. mouth discomfort.
   b. oral inflammation.
   c. sore throats.
8. The glands that secrete a thin, watery fluid that moistens and cleans the teeth are called:
   a. dental glands.
   b. mucous glands.
   c. parietal glands.
   d. serous glands.
9. The antimicrobial action of ethyl alcohol is reportedly linked to its ability to:
   a. denature and precipitate bacterial protein.
   b. inactivate enzymes within the cell.
   c. dissolve the protective lipid film around bacteria.
   d. interfere with cellular transport mechanisms.
10. Astringents exert all of the following actions on oral mucosa EXCEPT:
    a. act on pain receptors.
    b. decrease cell membrane permeability.
    c. form a protective film over the cells.
    d. precipitate proteins.
11. The components of carbamide peroxide are hydrogen peroxide and:
    a. potassium aluminum sulfate.
    b. sodium bicarbonate.
    c. zinc chloride.
    d. urea.
12. Which of the following has been proven to be a safe and effective antiseptic for use in the mouth?
    a. Benzalkonium chloride
    b. Hydrogen peroxide
    c. Povidone-iodine
    d. None of the above
13. The warning not to use the product when a bleeding problem exists or after surgery of the mouth or throat is most appropriate for:
    a. aspirin.
    b. benzocaine.
    c. carbamide peroxide.
    d. zinc chloride.
14. A product which is indicated for aiding in the removal of phlegm, mucus or other oral secretions is called a(n):
    a. anesthetic.
    b. demulcent.
    c. astringent.
    d. debriding agent.
15. Which of the following fits the description listed in question #14?
    a. Benzalkonium chloride
    b. Carbamide peroxide
    c. Phenolate sodium
    d. Zinc chloride

IRVING RUBIN RECEIVES REMINGTON HONOR MEDAL

Irving Rubin, editor and publisher of *Pharmacy Times* received the 1986 Remington Honor Medal at the 133rd Annual Meeting of the American Pharmaceutical Association (APhA) in San Francisco.

Pharmacist Rubin was honored as the 57th Remington Medalist, which is the profession's most prestigious award, created in 1918 by the APhA New York Chapter in honor of Joseph P. Remington (1847-1918), one of America's most influential pharmaceutical educators. The selection panel includes all living APhA past presidents and past chairmen of the APhA Board of Trustees.

Rubin reported in a grateful acceptance speech that his 45 years as a full time pharmacy editor had given him a rewarding and enjoyable opportunity to work on behalf of the pharmacy profession. He specifically emphasized a goal he would like to see achieved — one symbol to identify pharmacy in the United States. "By working together and creating 'One Symbol for Pharmacy' — which would be displayed prominently on the exterior of all pharmacies — we will perform a constructive service for the public and the professions — including the pharmacists of America."

Rubin is a (Ph. G. cum laude) graduate in 1936 from the Brooklyn College of Pharmacy. He subsequently earned a B.A. degree in English. He worked both in community and hospital pharmacy and served in the U.S. Army during World War II (1942-1946). Rubin started his career in journalism in 1938, acting as pharmacy managing editor of *American Druggist* and editorial director of the *Blue Book*. He joined Romaine Pierson Publishers as editor of *American Professional Pharmacist* in 1961 — whose title was changed in 1969 to *Pharmacy Times*. He was promoted to Corporate Vice President in 1980, but continues to serve as editor of *Pharmacy Times*.

OTC Industry Posts Reward

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The third case began Wednesday, March 19, 1986, when three OTC products manufactured by SmithKline Beckman Corporation were tampered with. The three products were Contac, a cold relief medicine; Teldrin, an allergy relief medicine; and Dietac, an appetite suppressant. While traces of warfarin, a rat poison, have been found in several packages of the products, no injuries have been reported.

SmithKline has withdrawn all three products from the retail market. Johnson & Johnson, maker of Tylenol, some weeks ago ended all production of OTC products in capsule form.

In addition to the $100,000 already available from Johnson & Johnson for each of the Tylenol cases (Chicago and Westchester County), The Proprietary Association, on behalf of the OTC medicines industry, if offering additional rewards totaling $700,000 for information leading to the arrest and conviction of the person or persons responsible for criminal tampering as follows:

- $300,000 for the March 1986 poisoning of Contac, Teldrin and Dietac in Houston and Orlando;
- $200,000 for the February 1986 Tylenol poisoning in Westchester County; and
- $200,000 for the September-October 1982 Tylenol poisonings in Chicago.

MARRIAGES

TAMMY LYNN KINNEY and Ronald B. Black were married on Saturday, December 28, 1985 at the West Raleigh Presbyterian Church.

The bride is a 1985 graduate of the University of North Carolina School of Pharmacy and is employed by Durham County General Hospital. The groom is an attorney and practices with the law firm of Johnson, Gambel, Hearn and Vinegar in Raleigh. The couple make their home in Raleigh.

Jean Morse, President of the Woman's Auxiliary of the NCPhA, who will preside over Auxiliary activities at the annual meeting in Greensboro

Classified Ads

(continued from page 36)

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3. a b c d	*6. a b c d*	*9. a b c d*	*12. a b c d*	*15. a b c d*

Evaluation ☐ Excellent ☐ Good ☐ Fair ☐ Poor

How long did it take you to read the article and complete the exam? _____

LETTERS

March 20, 1986

Dear Al:

In response to many inquiries, the following is a series of questions and answers concerning Upjohn's development of the use of minoxidil as a topical solution for hair growth. This information also responds to often-asked questions from physicians and pharmacists about the use of LONITEN® Tablets (minoxidil) in extemporaneous topical formulations. The main purpose in disseminating this information is to provide an increased level of understanding and awareness of Upjohn's position regarding the current prescribing and dispensing of minoxidil in compounded topical solutions.

Question 1: What is the status of Upjohn's program to develop REGAINE® Topical Solution as a topical minoxidil product?

In 1977, The Upjohn Company began a formal project to explore the possibilities for using minoxidil topically to grow hair. In 1983, Upjohn began a study involving more than 2,300 volunteers in 28 locations around the United States. This multicenter study, completed in 1985, was designed to assess the efficacy of REGAINE Topical Solution in the treatment of male pattern baldness. Its completion marked the end of Upjohn's first phase of the clinical development of topical minoxidil.

After completion of the analysis of the data from this study and a thorough evaluation of the safety and efficacy of topical minoxidil under the conditions of the study, Upjohn filed a New Drug Application (NDA) with the Food and Drug Administration (FDA) on December 19, 1985.

Additional clinical studies of REGAINE Topical Solution are currently in progress, studying the effects of this drug for a number of indications in addition to male pattern baldness. Upjohn expects to be in a position to comment on these studies at some future date.

Question 2: What are Upjohn's general concerns over extemporaneously formulated topical minoxidil preparations?

Over the past few years many news reports concerning the REGAINE development program have appeared. Some of these reports have been extremely optimistic concerning the clinical potential for REGAINE Topical Solution. In spite of this enthusiasm, Upjohn has consistently cautioned interested parties that the topical use of minoxidil has not yet been approved by the FDA as being safe and effective for hair growth.

The NDA for REGAINE Topical Solution, like all NDAs, is required to contain information on manufacturing practices and quality control procedures. Strict adherence to FDA-approved manufacturing and control procedures will be required of Upjohn when and if REGAINE Topical Solution is approved for marketing by the FDA. Quality control, with its attendant implications for both safety and effectiveness, cannot be taken for granted. Upjohn's experience in the clinical evaluation of REGAINE Topical Solution clearly indicates the need for consistent formulation of the drug in compliance with Good Manufacturing Practices as set forth in regulations of the FDA. Equally important, the drug must be accompanied by adequate instructions for use.

Reports appearing in the media have suggested that non-Upjohn sources of topical minoxidil solutions available from time to time over the past several years have varied widely in composition. Many of these non-Upjohn sources of topical minoxidil are apparently derived from reformulation of Upjohn's LONITEN Tablets. Patients using topical minoxidil under such conditions have no assurance of attaining effects comparable to those experienced under the conditions of the Upjohn clinical trials of REGAINE Topical Solution.

Upjohn has been and continues to be concerned that the availability of non-Upjohn sources of topical minoxidil solutions will adversely affect the introduction of REGAINE Topical Solution when and if approved by the FDA. As a result, Upjohn has been and is taking steps to discourage extemporaneous topical formulation and use of minoxidil. One recent step has been the revision of the package insert for LONITEN Tablets.

Question 3: What does the package insert for LONITEN Tablets indicate concerning the use of minoxidil for hair growth?

Upjohn's package insert for LONITEN Tablets contains an express and unambiguous warning against use of the product for hair growth.

The package insert for LONITEN Tablets,

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DICKINSON'S PHARMACY

by Jim Dickinson

Honest Joe's Quality Used Drugs. "There's no such thing as ethical or 'good' diversion," testified Charles M. West, executive vice president of the National Association of Retail Druggists, on Capitol Hill December 6. It wasn't a groundbreaking statement — an FBI witness had said pretty much the same thing a month earlier — but it was still the only way to say it.

If you pushed him, retail pharmacy owner West would probably admit that somewhere along the line he, too, has considered selling diverted drugs. Samples obtained surreptitiously from a detailman or, worse, a "distributor," and dispensed to a patient are still diverted.

I'm honest, though — and I know you're as ethical as a clergyman. We wouldn't let a patient touch a single capsule or tablet that we didn't *know* was pure, straight, A-OK, from a reputable source. Would we?

But wait a minute. It's that very sense of self-righteousness and consolation that exposes the entire profession to devastating loss of hard-earned and well-deserved public confidence in the current prescription drugs diversion scandal.

As long as there's a single pharmacist who's willing to break open a sample pack of any kind and mix its contents in his stock bottle, there's a cracked door open somewhere to someone less scrupulous to slip something else past.

As congressmen and senators *and reporters* are slowly learning from the unfolding diversion scandal testimony, it's the atmosphere of unregulated, "gray" area, bent-rules ethical acceptance that makes room for the beginnings of evil. That evil at its worst includes fake contraceptives that don't work and lead to abortions or unwanted and abused children, contaminated samples repackaged in gasoline spills on garage floors or in asbestos dust in filthy old attics, and the sale of sub-potent, long-expired lifesaving medicines that can no longer save lives or that can actually kill.

If you, a fully qualified pharmacist, don't look to *see* those shocking and unthinkable evils lurking behind nice, original manufacturer pack samples, how do you expect some of the unqualified people further back along your supply-line to see them?

And that's the catastrophe that's waiting to happen to pharmacy, health care and the American people in the diversion scandal. Congress knows it. What everyone's terrified of is that the mass media will tell the whole country before the loopholes are closed off by new measures, including heightened professional awareness in addition to legislative remedies like a ban on sampling and discriminatory pricing.

It's not as if pharmacy didn't have its own self-interest to protect in opposing sampling, without having to be bludgeoned into action by the diversion scandal. Think how sampling inevitably "trains" prescribers for that approaching time when the oversupply of physicians will drive them to largescale dispensing in order to survive in the medical marketplace.

But it's "good, ethical" diversion of nonprofit hospital drugs *and* samples that's getting the attention now.

Other advanced countries comparable to our own, such as Britain and Germany, don't have U.S.-style diversion because samples and drug prices are government-controlled. We have a free market without those controls. Anything goes, and you do it, too.

We have diverters, whose integrity is comparable to the used-car dealer's — Honest Joe's Quality Pre-owned Drugs. Only one original owner. Genuine low mileage. Free "loaner" drugs during warranty service. Trade-ins accepted.

Let the buyer beware!

This feature is presented on a grant from Mylan Pharmaceuticals, in the interest of promoting the open discussion of professional issues in pharmacy. Mylan Pharmaceuticals accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of Mylan Pharmaceuticals.

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Letters

(continued from page 33)

under the PRECAUTIONS section, item 10, provides the following:

> Use of LONITEN Tablets, in any formulation, to promote hair growth is not an approved indication. Clinical trials are in progress and are designed to determine efficacy, dosage, duration of treatment, and actual side effects. Pending completion and analysis of these trials, efficacy, dose and duration of the therapy are not known. Because systemic absorption of topically applied drug may occur and is dependent on vehicle and/or method of use, extemporaneous topical formulations made from LONITEN should be considered to share in the full range of CONTRAINDICATIONS/WARNINGS/PRECAUTIONS/AND ADVERSE REACTIONS listed in this insert. In addition, skin intolerance to drug and/or vehicle may occur.

Question 4: What is the current patent position of Upjohn regarding REGAINE Topical Solution?

A patent was issued to Upjohn in 1979 (United States Patent No. 4,139,619) claiming the topical formulations of minoxidil, including the drug REGAINE Topical Solution itself. The claims in the patent also cover the method of using minoxidil for hair growth. A second patent with related claims is expected to be issued within the next several months. Both patents will expire in 1996.

Question 5: How does the Upjohn patent position relate to the traditional freedom of physicians in prescribing drugs?

Upjohn is aware of the traditional prerogative of physicians to select and make available appropriate treatment for their patients without outside interference with the patient-physician relationship. Historically, Upjohn has not used its patent rights to interfere with this relationship by preventing an individual physician from privately treating a patient with a therapy patented but not marketed by Upjohn. Nonetheless, the use of the advertising media to promote the availability of patent-infringing topical minoxidil products is now being undertaken by many individuals in a manner that directly challenges Upjohn's patent position. Because of the substantial investment Upjohn has made in the development of REGAINE Topical Solution, the curtailment of patent infringing activity through the assertion of Upjohn's patent rights has become a high priority for Upjohn.

The patent infringement activities mentioned above may also adversely affect the introduction of REGAINE Topical Solution when and if approved by the FDA.

Question 6: What does Upjohn currently regard as an "infringement" of its patent rights?

While in many cases they do so unknowingly, physicians who prescribe, pharmacists who formulate, and patients who use topical minoxidil formulations are infringing and/or inducing the infringement of Upjohn patent rights. Infringement takes place even if minoxidil is purchased from Upjohn in the form of LONITEN Tablets. Purchase of LONITEN Tablets carries with it no license, either express or implied, under any patents of Upjohn.

I trust that you and your associates will find this information useful.

Sincerely,

Jack M. Newcomb
Director, Pharmacy and Trade Relations
The Upjohn Company

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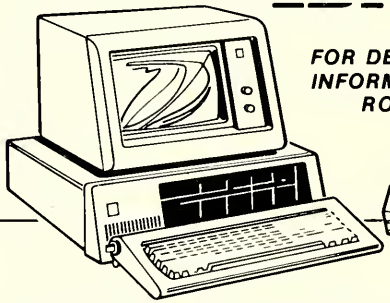

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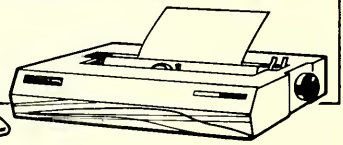

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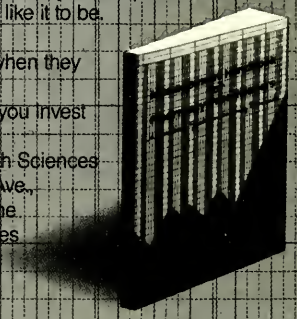

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REMARKS BY SARA FRANKO, STAFF ASSISTANT SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS COMMITTEE ON ENERGY AND COMMERCE 20th ANNUAL SOCIO-ECONOMIC SEMINAR FEBRUARY 19, 1986

The problems associated with prescription drug diversion have been a focus of efforts by the Subcommittee, and particularly its Chairman, John Dingell, over the past year. The investigation has confirmed initial indications that drug diversion poses a serious threat to the health and safety of the American public.

As many of you may be aware, drug diversion refers to the operation of a wholesale secondary market for prescription drugs in the U.S. This secondary market is supplied from a variety of sources other than directly from the manufacturer or an authorized distributor. Some of these sources may be legal and some certainly are not. The principal danger arising from this submarket is its potential for use by unscrupulous individuals as a dumping ground for stolen, counterfeit or adulterated medicines. This is exactly what happened in the recently publicized cases of the distribution of counterfeit Ovulen 21 birth control pills and Ceclor antibiotic capsules. Fortunately, while diversion is commonplace, documented instances of counterfeit or adulterated pharmaceuticals reaching consumers through normal retail outlets are few.

Photo by Colorcraft

Sara Franko

However, the recent distributions of counterfeit Ovulen 21 and Ceclor are irrefutable evidence that the drug distribution system contains serious loopholes which allow the introduction and eventual retail sale of substandard, ineffective or counterfeit pharmaceuticals. The Subcommittee's investigation and the legislative recommendations which will be considered during the next few months are designed to restore the integrity of the distribution system and ensure accountability over the sources and quality of prescription drugs.

Before I discuss in more detail the major issues involved in drug diversion, I think it would be useful to clarify the Subcommittee's role in the legislative process within Congress. The Subcommittee is the investigative arm of the Committee on Energy and Commerce in the House of Representatives. The Committee, which handles nearly forty percent of all legislation in the House, has a wide jurisdiction which includes public health and consumer protection, as well as interstate and foreign commerce, national energy policy, and biomedical research and development. The Committee is divided into five legislative subcommittees which mark up and vote on legislation. The Oversight Subcommittee does not consider legislation; instead, it examines the implementation and effectiveness of laws and investigates matters within the Committee's jurisdiction. Recent investigations into the failure of the Environmental Protection Agency to implement hazardous waste laws, and overcharging of the Government by General Dynamics and other defense contractors are examples of other inquiries undertaken by the Subcommittee.

Following its investigations, the Subcommittee refers any findings or recommendations regarding legislation to the appropriate legislative committee(s). In the case of legend drug diversion, the Oversight Subcommittee is currently working with the Subcommittee on Health and the Environment, whose Chairman is Congressman Henry Waxman from California.

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Diversion

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The drug diversion inquiry grew out of a broad review of unfair and illegal foreign trade practices which was commenced in 1983. The Subcommittee found that a very large number of American products and technologies were being copied by unauthorized foreign manufacturers. The products were being sold in foreign countries and in the United States. These counterfeits were usually substandard in quality, often presented serious hazards to consumers, and tarnished the reputation of the legitimate manufacturer. Pharmaceuticals and sundries were included in the range of counterfeit products identified by the Subcommittee.

One example provided to the Subcommittee during these hearings on unfair foreign trade practices involved the 1978 recall by the Food and Drug Administration of heart pumps used in over two hundred hospitals throughout the country. The $357 heart pumps were believed to contain potentially dangerous counterfeit components worth only $8 each. In another case, the Subcommittee learned that certain Vick's products were being counterfeited and sold abroad. Specifically, Vick's Formula 44 cough medication had apparently been manufactured in the jungles of Indonesia without sanitation or quality control.

While a number of such sales of counterfeit pharmaceuticals had been documented abroad, a very limited investigation originally suggested the problem was not present to any serious degree in the United States. Then, in October 1984, it was discovered that more than one million Ovulen 21 birth control pills had been counterfeited, imported from Central America, and widely distributed throughout the United States. This discovery, and particularly the speed and ease with which the counterfeit pills were funneled through the wholesale system, focused the Subcommittee's attention on counterfeit and diverted pharmaceuticals.

In late 1984, the Subcommittee began its drug diversion inquiry by collecting information on the operation of the wholesale market for pharmaceuticals. As part of this effort, the Subcommittee surveyed the larger manufacturers and a number of wholesale druggists. The staff talked to other trade associations, state pharmacy boards, hospital pharmacists and academics. Five days of public hearings were held last year. At these hearings, witnesses from the public and private sectors, including diverters, private investigators and representatives from all major segments of the pharmaceutical industry, presented their views on drug diversion and suggested solutions to eliminate the hazards associated with diversion practices.

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The most comprehensive information supplied to the Subcommittee came from the testimony of officials responsible for the Atlanta undercover investigation into drug diversion. The sting operation, code named "Pharmoney," was conducted by the U.S. Attorney in Atlanta, the Federal Bureau of Investigation, and the Georgia State Drugs and Narcotics Agency. On August 6, 1985, the U.S. Attorney in Atlanta, Mr. Larry Thompson, announced the filing of criminal informations charging nearly fifty individuals and companies with violating various fraud statutes and laws pertaining to the adulteration or misbranding of pharmaceuticals. Criminal informations are filed preparatory to the acceptance by a court of guilty pleas. Most of the persons who were charged pled guilty, and additional informations have been issued as part of the continuing investigation. Some defendants were given jail sentences of as much as five years, while others received extensive community services and fines. The defendants included manufacturers' sales representatives, doctors, registered pharmacists, drug wholesalers, and employees of hospitals and clinics. The U.S. Attorney has indicated that approximately forty more individuals and companies are targets of the investigation.

The Pharmoney operation involved the establishment of a fictitious affiliate of a hospital pharmacy management firm. An undercover FBI agent and a registered pharmacist from the Georgia Drugs and Narcotics Agency, acting on behalf of the fictitious entity, began to build a reputation as traders in diverted pharmaceuticals. Once established, the operation received unsolicited telephone calls from previously unknown individuals who expressed a strong desire to engage in the sale, trade, or exchange or diverted pharmaceuticals.

Scope of the Problem

The Pharmoney investigation and the Subcommittee's inquiry have developed considerable evidence pertaining to the operation of the drug diversion market. It is apparent that diversion is a significant and growing problem. It extends nationwide. The U.S. Attorney in Atlanta testified before the Subcommittee in October that, "At least one drug store in *every* city, town and village involved in the FBI investigation was found to be dispensing [diverted, adulterated and misbranded] medications." These drugs included almost any type of non-controlled prescription medications, including blood pressure, heart and ulcer medications, as well as thyroid pills, birth control pills and antibiotics.

The principal incentive for individuals and companies to divert medicines can be found in the multi-tier pricing structure for pharmaceuticals. Manufacturers generally sell medicines at prices well below wholesale to their institutional customers. As a result, huge profits can be realized from the resale of prescription drugs which have been purchased at a discount, often a very substantial discount below the average wholesale price. Drug diversion often involves a scheme in which false representations are made to drug manufacturers that pharmaceuticals are being purchased for use in hospitals and charities, or for export purposes, in order to obtain low purchase prices. The drugs are then diverted from their intended use to resale at substantial profit for ultimate dispensing to consumers. Among other problems, it is difficult to trace such diverted medicines in the event of a recall.

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Diversion

Continued from page 7

Drug diversion is a very profitable business. The FBI estimated that annual diversions of the drugs involved in the Pharmoney investigation amounted to $½ billion dollars. The FBI purchased or seized goods worth over $600,000 during the course of the investigation. One subject, an unlicensed wholesaler/diverter, was videotaped during a conversation in which he told the undercover FBI agent, "I sold a hundred and eleven thousand dollars last week." Moreover, the undercover operation indicated that the demand for diverted medicines far exceeds availability. According to the FBI, "subjects constantly complained that they wanted larger quantities."

It is important to note here that we have no reason to believe that the cost savings are passed along to the consumer. Instead, the medicines are often resold through many levels of the distribution chain, with each intermediary extracting a profit. According to the U.S. Attorney, the initial diverter usually doubles his money.

The Pharmoney investigation revealed that, in an attempt to avoid detection, diverters often ship their products across country or abroad. The undercover operation discovered medicines which had been stored in warehouses, garages, attics, basements, ships and loading docks. There is a serious potential for medicines which have been shipped outside normal channels, and without benefit of inspection, to be outdated or damaged by excesses of heat or cold.

The Food and Drug Administration mandates the safeguards which are to be used in handling and packaging drugs. These requirements include, among others, the use of sterile hand, head and body coverings and rooms with special air filtering systems. Diverters often ignore these standards, remove drugs from their original packaging and labeling under less than sanitary conditions and place them in unauthorized containers. In one segment from the videotapes of the FBI investigation which was shown at a Subcommittee hearing, we viewed an individual shucking pills, that is removing them from their packaging, while drinking beer, obviously an unsanitary practice.

Other similarly shocking violations were outlined by Mr. Richard Allen, the Georgia pharmacist who worked undercover in the FBI operation. Mr. Allen discussed the experience of the undercover FBI agent with regard to a pharmaceutical company sales representative who was charged in the drug diversion investigation. The FBI agent accompanied the sales representative to his home where he kept thousands of dollars worth of expired medicines in the attic. On one particular morning in August, the FBI agent recorded the temperature in this attic at 103 degrees. Manufacturers later informed the FBI that the medicines which had been stored in the attic (assuming they were not outdated) should not have been exposed to temperatures exceeding 86 to 90 degrees, and some should have been refrigerated. The FBI agent witnessed the sales representative place 44,000 thyroid pills, 90 percent of which were expired, into a brown grocery bag, drop some of the pills in the fiberglass attic insulation, retrieve the pills and put them back into the bag. On another occasion, in the presence of the FBI agent, the same sales representative place 8500 capsules into a paper bag, and then into a van. The van was forced to stop suddenly, and the pills spilled out of the sack and onto the floor of the van. When they pulled into a gas station to retrieve the capsules, some of the pills fell into an oil slick on the pavement of the filling station. The sales representative again retrieved the pills, commenting that the oil coating would make them easier to slide down the old folks' throats.

Companies Specializing in Diversion

Participants in the diversion market cover a broad range in size, volume of sales, and type of merchandise. In some cases, the firm's entire business is to buy and sell diverted merchandise, while in other cases only a small percentage of the company's activities involve such goods.

The larger firms tend to deal in volume, rarely handling orders below case lots, and generally do not purchase samples. However, mere size is no guarantee of quality. Several of the larger, well-known diversion firms bought counterfeit Ovulen 21 in 1983–84. Despite this experience, some of these very same firms also bought the counterfeit Ceclor antibiotic.

Many of the individuals who were the subject of criminal charges in the Atlanta investigation have been associated with small or medium-sized companies. Thus, abuses associated with drug diversion clearly bear no relationship to the size of the firm or the volume or type of merchandise handled by the company.

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Diversion

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Sources

The diversion market is supplied from a range of sources. They include: (1) nonprofit institutions that buy in excess of their needs and resell the surplus; (2) samples that are intended for use in health care institutions or by doctors that are sold to wholesalers instead; (3) foreign counterfeits; (4) pharmaceuticals that are produced in the United States, sold to foreign buyers, and re-exported back to the U.S.; (5) foreign produced goods that are relabeled and/or repackaged prior to sale in the U.S.; (6) companies or individuals that obtain pharmaceuticals from manufacturers through false or fraudulent pretenses; and (7) stolen merchandise.

There are also a number of legal sources of discounted product to wholesalers that deal in the diversion market. These include drugs bought at special prices or prior to price increases and resold when the price goes up; dump sales by manufacturers of overstock or discontinued items; promotional sales; and special price sales for large volume purchases. However, by the time the pharmaceuticals reach the retail pharmacy, these sources of supply often cannot be separated from one another. As a result, most wholesalers and retailers cannot, with absolute certainty, protect themselves against buying pharmaceuticals that may be adulterated, subpotent or ineffective. It almost goes without saying, then, that the American consumer is similarly incapable of ensuring that the medications they purchase are safe and effective.

Nonprofit Institution Diversion

Nonprofit institutions that purchase pharmaceuticals beyond their needs and resell the excess to the wholesale market help fuel the diversion market. The practice has existed for many years. Recently, the volume of merchandise and the number of diversions from nonprofit institutions appear to have increased dramatically.

Such resales are economical because nonprofit or charitable institutions, under an exemption to the price discrimination prohibitions of the Robinson-Patman Act, can purchase medicines "for their own use," at a discount. Such resales provide an unfair competitive disadvantage to wholesale and retail pharmacists who can not obtain the same discounts. The resales of pharmaceuticals sold "for their own use" to nonprofit health care institutions may be illegal under the Robinson-Patman Act. Regardless of the tax status of the institution, such resales probably constitute fraud against the manufacturers when any health care institution is

Photo by Colorcraft

Seminar Participants Lawrence C. Weaver, PMA; Moderator Jean Gagnon; Ronald J. Streck, National Wholesale Druggists Association.

allegedly purchasing the goods "for its own use." Certainly, the practice contributes to the lack of accountability over product source in the diversion market.

An entire industry has emerged to solicit both profit and nonprofit hospitals to purchase excess pharmaceuticals using their special discount. The products are then immediately resold to a broker or wholesaler for ultimate retail sale.

Samples

Drug samples have been another traditional source of product for the diversion market. Many of the criminal acts identified in the FBI investigation involved the diversion of samples into the wholesale market for ultimate retail sale. Sample markings and packages had to be altered for this scheme to succeed. The U.S. Attorney told the Subcommittee that sample markings had been removed from the tablets, pills and packaging by the use of razor blades, acetone, fingernail polish remover, rubbing alcohol, and even an electric eraser. Moreover, the drugs were separated from their packaging and labeling and placed into unsanitary containers such as baggies, open boxes, grocery bags, garbage bags, cellophane bread wrappers and used soft drink bottles. The result was that the medicines became contaminated, did not have expiration dates and could not be traced in the event of a recall.

The investigation identified thirteen medical doctors who wrote manufacturers requesting pharmaceuticals for their professional disbursement. Instead the samples were sold to diverters. The investigation also established the fact that a number of pharmacists, sales representatives and even drug company executives were dealing in samples. In a number of cases, the samples were beyond their expiration dates, some by as much as five years.

Shocking as this is, The Pharmoney investigation did not really uncover anything new. Dr. John Schlegel, President of the American Pharmaceutical Association, testified that his association had been seriously concerned about the misuse of samples for over forty years. Also, according to the testimony of Mr. Eddie Burklow, who pleaded guilty in the investigation, the abuse of samples had been commonplace during his eighteen years as a sales representative and executive in the pharmaceutical industry. Mr. Burklow noted that sales representatives use samples as a marketing tool, sometimes providing excess quantities of samples to doctors or pharmacists to "sweeten" deals involving the purchase of brand name or over-the-counter drugs, to induce the physician to prescribe a particular company's product, or even to persuade a pharmacist to give preferred shelf space to an item. Sales representatives and doctors were also said to trade samples to pharmacists for merchandise or other drugs.

Existing Federal laws regulating the dispensing of samples do not prohibit the purchase, sale or trading of samples. The boundaries of Federal law are crossed when samples are removed from their required packaging and labeling, or are adulterated. If the samples are controlled substances, which is usually not the case, Federal law specifies dispensing and recordkeeping requirements. According to Dr. Schlegel, in 1984, only twenty-eight states had regulations dealing with sample drugs, and even those varied widely. Only one state, Pennsylvania, explicitly requires that sample drugs be labeled with information about the name, quantity, and instructions for use before they are dispensed to a patient.

Counterfeits and Reimported Drugs

Counterfeit and reimported drugs have also been identified as a source of product for the diversion market. In December 1984, the Subcommittee conducted a confidential survey of the large brand name pharmaceutical manufacturers in the United States to gain information on counterfeit or intentionally mislabeled prescription drugs. The survey disclosed significant counterfeiting of pharmaceuticals and instances of patent infringement abroad. In the survey, manufacturers identified Hong Kong, Taiwan, the Philippines, Mexico, Singapore, Thailand, India, Brazil, Italy, Malaysia, Colombia and Nigeria as sources of counterfeit medicines. The bogus drugs included anti-inflammatory and anti-infective agents, antibiotics, sedatives, and even counterfeit polio vaccine. Dried milk and sugar, talc and corn starch, flour, and wheat paste were among the substances which had been substituted for the actual medicine.

The counterfeiting of U.S. brand name pharmaceuticals by foreign persons in foreign countries poses a threat to the health and safety of consumers in those nations. In most instances, the counterfeits are subpotent or ineffective, and may even be contaminated. These products steal

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Diversion

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markets from American companies and unfairly tarnish the good name of the legitimate product and company in the foreign market.

The secondary market for prescription drugs provides a ready means to distribute such counterfeits in the United States. In particular, the reimportation of American-produced goods which have been exported, has provided the cover for the importation of counterfeit pharmaceuticals in at least two cases — G.D. Searle's Ovulen 21 birth control pills and Eli Lilly's Ceclor antibiotic capsules. The Ovulen was entered through the ports of Miami and New York from Panama, and the Ceclor was imported from Singapore through Miami and Boston. The Ceclor did contain Eli Lilly's active ingredient, but the capsules, labels, lot numbers and packaging were all fake. In both cases, distribution throughout the United States occurred in a matter of days.

A significant volume of such reimported goods, classified on Customs forms as "American Goods Returned," enter the United States every year. Many of these originate from or near countries with counterfeiting problems, posing the real danger that more counterfeits could enter the distribution system. Furthermore, even though a large number of drugs classified as American Goods Returned are the legitimate product of manufacturers in the United States, they still present a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping. Also, the true source may have been altered by repackaging or poor recordkeeping.

The ready market for reimports has also been the catalyst for the perpetration of a continuing series of frauds against American manufacturers. Many such products appear to be purchased under false pretenses with the intent that they be reimported. Drugs which have been purchased at discounts allegedly for shipments to birth control

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clinics in places such as Haiti, Nigeria, or Eastern Europe have been returned to the United States for retail sale. In another instance, a San Francisco wholesaler bribed an official in a government hospital on the island of Saipan to purchase excess quantities of pharmaceuticals at the government discount and then divert the excess to the wholesaler. The scheme was discovered when the pharmaceutical company realized the hospital had purchased enough birth control pills for every man, woman and child on the island.

A major scam operated from 1975 through 1978 conned manufacturers into selling or donating millions of dollars worth of pharmaceuticals to bogus charities. The goods were supposed to go to needy peole in the Third World, but were instead sold at retail for substantial profit in Florida. Large pharmaceutical companies sold medicines worth $2.5 million to the conspirators. The operation involved the establishment of branches of legitimate charities, the creation of a front organization, and the bribery of an official of another charity.

According to testimony at the Subcommittee's hearings, some manufacturers may have assisted these schemes either through indifference or collusion. Company sales personnel may be more concerned with making the sale than about the dangers of drug diversion. In other instances, the manufacturer's overseas sales representatives were actively involved in the diversion. However, the fact that elaborate schemes have been devised with the purpose of misleading manufacturers indicates that such practices were not tolerated, or expected to be tolerated, by the manufacturers.

Until recently, American Goods Returned received minimum scrutiny from the Food and Drug Administration and the U.S. Customs Service. In fact, such shipments from South America, Asia or Africa were routinely permitted to enter the United States without any examination of the paperwork, much less physical inspection. However, because of the hazards uncovered by the Subcommittee's investigation, Chairman Dingell requested in August that the Customs Service and the FDA halt all imports of American Goods Returned until they could be tested for safety and efficacy. As a result, complete documentation is currently required before medicines can be entered as American Goods Returned, and testing at an independent laboratory is required if doubt exists as to conditions of manufacture, storage, shipment, packaging or labeling. It is now more difficult to enter foreign counterfeits through normal channels. However, the increased surveillance of pharmaceuticals attempting declared entry into the United States will not eliminate the practice of smuggling those goods into the U.S.

Recommendations Made to the Subcommittee

In December of 1985, the Subcommittee held a hearing to consider legislative, regulatory and enforcement solutions to protect the public health from the threat posed by prescription drug diversion. Seven trade associations representing pharmaceutical manufacturers, wholesalers, retail druggists, chain drug stores, pharmacists, hospital pharmacists and state boards of pharmacy offered their legislative suggestions to the Subcommittee.

These witnesses provided a variety of remedies designed to combat the dangers or drug diversion. The problem of sample abuse received a good deal of attention. Several of the trade associations suggested replacing the current system of sample drug distribution with a coupon or complimentary prescription system. Patients could obtain free prescriptions directly from a retail pharmacist upon presentation of a coupon supplied by their physician. The enactment of legislation making it a Federal offense to knowingly buy or sell pharmaceutical samples was suggested by the Pharmaceutical Manufacturers Association, which favored retaining the present sample disbursement system.

The witnesses also addressed the problems associated with institutional resales. Some suggestions in this area included the establishment of Federal sanctions against the resale of prescription drugs by nonprofit institutions, clarification of the nonprofit exemption to the Robinson-Patman Act to ensure that only the most needy organizations could obtain discounts, and greater Federal Trade Commission enforcement of antitrust violations by nonprofit health care institutions.

Other recommendations included: (1) banning the reimportation of pharmaceuticals into the United States; (2) instituting a single price policy in the market for prescription drugs; (3) increasing the penalties against counterfeiting, adulteration and theft of pharmaceuticals; (4) requiring all levels of the distribution chain to

(Continued on page 15)

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Diversion

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verify the legitimacy of the drug and its distribution; and (5) increased enforcement of state laws governing the licensing and registration of wholesalers and retailers.

Accountability

The widespread availability of merchandise from secondary sources and the highly competitive nature of the wholesale and retail pharmaceutical markets create tremendous economic pressure to obtain merchandise at the lowest possible price. For a company to do otherwise is to lose market share and, over time, go out of business. Thus, the realities of the wholesale marketplace have combined to create a system in which a large amount of attractively priced pharmaceuticals are constantly available, some of which are not safe or effective. The physical movement, conditions of storage, and, in some cases, even the origin of much of this merchandise is unknown to the first, second or third level buyer.

In essence, the problem with merchandise in the secondary market is the lack of accountability. The same wholesaler that buys at a volume discount or takes advantage of a special manufacturers' offer may also buy subpotent or counterfeit drugs from overseas. At present, purchasers of diverted goods subsequent to the first purchaser usually do not know how or from where the goods were obtained. The Subcommittee's recommendations will be focused on eliminating this dangerous lack of accountability and restoring public confidence in the drug distribution system in the United States.

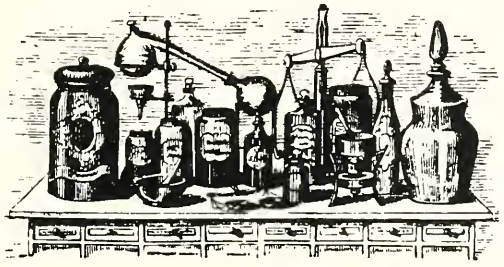
The Subcommittee's report on the drug diversion investigation is expected within the next two months. The legislative recommendations will be introduced shortly thereafter.

CONGRESSMAN LUKEN INTRODUCES BILL TO COMBAT DRUG DIVERSION

Congressman Tom Luken (D-Ohio) has introduced legislation (H. R. 4482) which would help to identify sources of diverted, substandard or mislabeled prescription drug products in the distribution system. The Luken bill is in response to health and safety issues that have been raised by a House Oversight Subcommittee which has conducted a series of hearings on problems relating to diverted pharmaceutical products and counterfeit medications.

Noting that non-profit health care facilities are becoming a major source for diverted drugs, the Luken measure would require certain non-profit institutions to register annually with the Food and Drug Administration (FDA). Under the proposal, non-profit hospitals and other health care facilities would be required to disclose information to FDA about the quantity of pharmaceutical products that were purchased at preferential prices and to provide information on the identity of the persons to whom the products were resold. The legislation would not prohibit non-profit entities from buying pharmaceutical products at preferential prices, but establishes new standards of accountability. The Ohio Democrat pointed out that non-profit entities that do not resell drugs would not be affected by the proposal other than the basic requirement to file a report with FDA.

Rep. Luken, who serves on the House Energy and Commerce Committee which will have jurisdiction over the bill, emphasized that the legislation would not restrict a non-profit hospital's ability to dispense drugs to its patients. However, he added that "those facilities that are buying pharmaceuticals above and beyond what they dispense to their patients and resell the excess to diverters will have to inform the FDA about these transactions."



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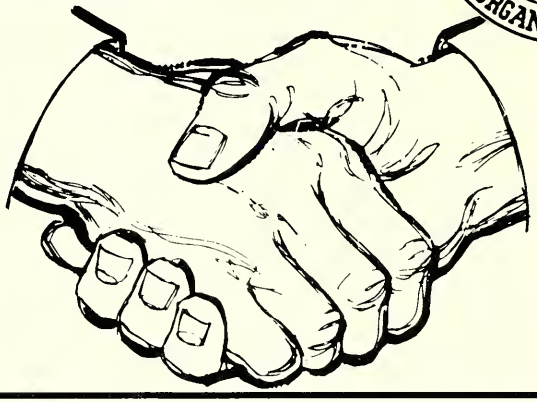

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THE ECONOMIC INCENTIVES OF CLINICAL PHARMACY SERVICES AND THE INDEPENDENT

by Karen J. Harper

The market for self-help health care products is expected to expand from $1.2 billion in 1983 to $5.7 billion in 1988, which represents a compound annual growth rate of nearly 37%. The growth of this market and the increasing trend toward self-medication can be utilized by the independent retailer to generate more revenue through the implementation of clinical services. The purpose of this paper is to examine how the provision of clinical pharmacy services can have significant economic benefits for the Independent.

To understand how clinical services can generate more revenue, one must first examine what clinical services the community pharmacist provides and the economic incentives of each service. Individual community pharmacists provide such clinical services as hypertension detection and prevention, diabetes screening and counseling, family planning/STD control, alcoholism awareness, childhood immunization and non-prescription drug counseling. The current economic incentive for performing preventative health activities in hypertension, diabetes and OTC counseling is high, whereas the other activities mentioned are intermediate to low.

I have chosen to discuss clinical services for hypertension, diabetes and OTC counseling in this paper for two reasons. First, community pharmacists play an increasing role in preventative health through individual counseling and through the activation of clients to practice good self care. For both diabetes and hypertension, the independent pharmacist plays a primary role in detection and a secondary role in the prevention of long term complications of the disease. The pharmacist also plays a major preventative health role in counseling patients regarding self-care and OTC products. Second, these services not only provide high financial incentives for the Independent, but also are cost-effective to the health care system as a whole.

Economic incentives for clinical services to hypertension patients are high. Pharmacists can and do charge directly for blood pressure screening services. It is not uncommon for pharmacists to charge $.50 to $2 per measurement. Improved compliance through blood pressure monitoring results in an increased antihypertensive prescription volume. The provision of these services will also bring new patients to the pharmacy, generating more traffic.

Implementation of clinical services in this area is especially important to Independents in North Carolina since it is estimated that 1.5 million people in this state have hypertension. In addition, 87% of this population do not have their hypertension under adequate control. Uncontrolled hypertension is the primary cause of heart disease and stroke, which are the first and third cause of death in North Carolina. The economic impact of long term complications for the state is drastic. In 1983, for example, 23,356 North Carolinians died of heart disease and stroke. Of these, approximately 6 thousand were between the ages of 19 and 65 and thus died prematurely. The reduction in manpower and cost of $266 million in health care per year for 74,000 disabled stroke patients is a substantial loss to the state. The community pharmacist in North Carolina thus plays a critical role in the treatment of hypertension by preventing complications and helping to alleviate this cost to the state.

The economic incentive for pharmacists to provide preventative health services to diabetics is also high. The market for insulin/oral hypoglycemic and urine testing products is currently estimated at $265 million and the syringe, needle and accessory market at $60 million per year. The market for blood glucose colorimeter devices is also potentially large. As authorized dealers of these devices, pharmacists gain the reputation as a diabetic specialist, attracting diabetic clientele. The economic advantages of cultivating the diabetic clientele are quite high when one considers that pharmacists, on the average, derive three times the revenue from diabetics as from other patients.

In North Carolina, 5% of the population (265,000) are diabetics. Since there are currently 1,849 pharmacies in North Carolina, 143 diabetics could be served by each pharmacy. Independents could promote diabetes control by establishing a diabetic care center in the pharmacy. The pharmacist could screen and counsel patients on the use of diabetic products in this center and bill the patient directly for this service.

The economic incentive for community pharmacists to counsel OTC purchases is also very substantial. Competent counseling results in

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Economic Incentives

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proper non-prescription drug purchases and repurchases. This could be a significant source of revenue for the Independent, since the non-prescription drug product business accounts for one-third of every dollar spent in pharmacies on medicine.

In conclusion, Independents should realize the economic incentives for the provision of clinical pharmacy services. The community pharmacist should specifically cater to that portion of the clientele who are diabetics, hypertensive and/or OTC users, where the economic incentive is high. In doing so, the Independent will reap significant economic gains. In the longrun, provision of such services will benefit both the patient and society through better health and decreased health care costs.

The Author is a student in the UNC School of Pharmacy.

NCPhA President and Moderator H. Shelton Brown and William L. Mincy, COO, Florida Pharmacy Providers Services Corporation, program participants in the Socio-Economic Seminar. Photo by Colorcraft.

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LOCAL NEWS

NORTHEASTERN CAROLINA PHARMACEUTICAL SOCIETY MEETS

Our second meeting of the Northeastern Carolina Pharmaceutical Society met on Wednesday, April 9 at Cobb's Restaurant at the Holiday Inn in Williamston.

Laurie Stoddard and Bob Hathaway of Lederle Laboratories sponsored our program. Our speaker was Charles Wayne Weart, Pharm.D Director of Pharmacy Education in Family Medicine of the University of South Carolina. Dr. Weart gave an excellent presentation "Hydertension: Past, Present, and Future".

There were 49 members present. Special guest included Pam Riddle and Stacie Taylor, fifth year pharmacy students: Bob Hathaway, Laurie Stoddard and Rick Hendrix of Lederle Laboratories: Our special guest Charles Wayne Weart, Pharm. D.

We would like to extend a special thanks to Lederle Laboratories for sponsoring our program.

Respectfully submitted by Michel Adams Sec. Treas.

PHARMACY CELEBRATES 30 YEARS

Gordon Manor Pharmacy, Winston-Salem, celebrated 30 years in business March 1, with an open house and reception for customers, patients and friends of the pharmacy. Door prizes were awarded as a result of registrations during the month of February.

GOLDSBORO

On January 8, Richard V. Kennerly was appointed to a 3 year term on the Board of Directors of the Wayne County Boys' Club. Richard has been active at the club for the last 3 years in the capacity of coach and assistant coach in many of the athletic programs offered at W.C.B.C. In addition, he is also Treasurer of the Parents' Club and works in close conjunction with the Executive Director in fund raising projects.

As an Eagle Scout himself, Richard is active in the Cub Scout program at St. Pauls United Methodist Church in Goldsboro where he is a member and Assistant Webelos Leader for Pack 2, Torhunta District, at St. Pauls.

Richard is the Director of Pharmacy Services at the Wayne County Health Department, one of the few counties in North Carolina offering full-time, in-house pharmacy services. He is married to the former Judi Campbell, a graduate of East Carolina University and teacher at Cherry Hospital. They have one son, Charles.

BIRTH

Born to Mike and Linda Woodard, a daughter Corie Michelle, on February 25, 1986 at Wake Medical Center Raleigh. Maternal grandparents are Mr. & Mrs. John Corey of Stokes. Paternal grandparents are Mr. & Mrs. Barney Paul Woodard of Princeton. Mike is a 1977 graduate of UNC School of Pharmacy.

DEATHS

Robert H. (Bob) Seaborn, Raleigh, died Sunday, April 20, at the age of 65. He had been in declining health for a long time. Seaborn was a former owner of Melvin's Pharmacy in Raleigh. He attended the Medical College of Virginia and was a graduate of the UNC School of Pharmacy.

Kodak Forms Pharmaceutical Division

The Eastman Kodak Company has formed a pharmaceuticals division to develop products and programs "that will enable Kodak to become a major contributor in the pharmaceuticals market," according to company officials.

Company representatives say that Kodak's strength in chemistry, its long-term commitment to life sciences and bio-technology, and its strong financial background should enhance its efforts to become a major pharmaceutical enterprise.

Current projects include research to develop anti-aging and antiviral compounds at the Nucleic Acid Research Institute in Costa Mesa and work with Elan Pharmaceuticals, an Irish firm, to develop advanced drug delivery systems. Kodak anticipates clinical trials of some of its pharmaceuticals to begin this year.

CORRESPONDENCE COURSE

ADVISING CONSUMERS ON COMMON EAR DISORDERS

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University, Ada, OH
and
J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati, Cincinnati, OH

Goals

The goals of this lesson are to:

1. describe the etiology and treatment of common ear disorders;
2. explain how to advise patients on self-medication of these disorders.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. show an understanding of how common ear disorders are contracted;
2. recognize effective OTC agents for these disorders;
3. explain the proper technique for instilling otic products;
4. decide when the patient should be referred to a physician.

Disorders affecting the ear are common. Pharmacists are routinely asked to recommend treatment for earaches, impacted earwax, "running ear," congested ears, or itching and irritation associated with infection.

During the fall and winter months, many prescriptions for antibiotics, decongestants and analgesics are written to treat otitis media (middle ear infection), especially in children. Otitis media is one of the most common medical disorders of children. However, there are no OTC products that effectively treat otitis media.

Self treatment of otic disorders is generally restricted to conditions of the outer ear. One exception is barotitis, the painful sensation that originates in the middle ear that is caused when an individual descends too quickly from a high altitude, such as in an airplane.

Otic pain is a general symptom that may result from a variety of conditions. It may also originate elsewhere and be referred to the ear following injury or trauma to the jaws, nasopharynx, tongue, tonsils or paranasal sinus area. Loose fitting dentures, eruption of molar teeth, or dental infection may cause pain around the ears. Poorly fitting ear plugs or hearing aids may likewise cause localized discomfort that will be interpreted as pain.

The Ear

The ear is divided into three sections: external, middle, and internal (Figure 1). The **external (outer) ear** includes the auricle (pinna) and ear canal. Its function is to receive and transmit sounds into the middle ear.

The skin and underlying subcutaneous layer lining the ear canal is thinner than elsewhere in the body. The skin is also tightly stretched. Therefore, the slightest inflammation will be interpreted as having greater intensity than a quantitatively similar inflammatory reaction elsewhere on the body. Pain originating in the tissue anywhere along the external ear may indeed be aggravating and uncomfortable. However, its intensity will not always accurately describe the actual extent or severity of the underlying condition.

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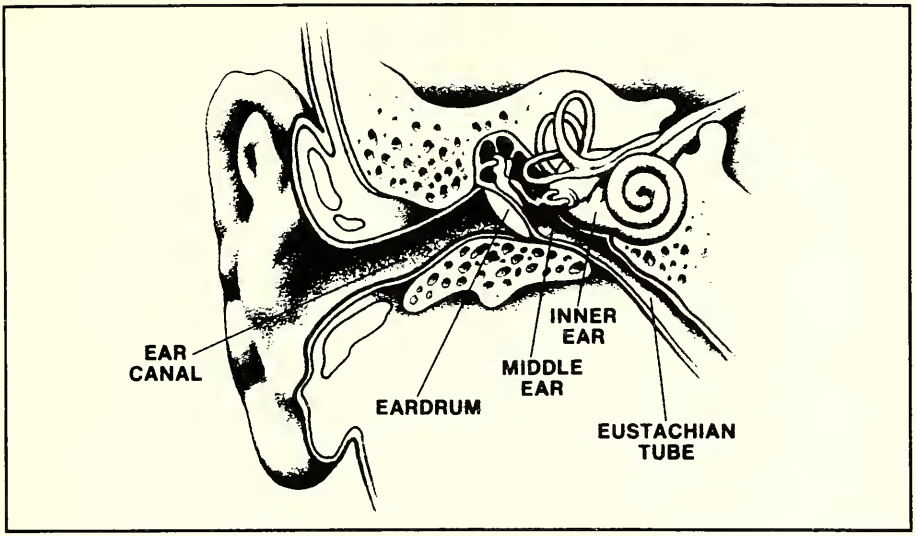

Figure 1. The ear.

The external ear is separated from the middle ear by the eardrum (tympanic membrane). This thin membrane is about 9 mm in diameter (about half the width of a dime). The eardrum is considered to be a part of the external ear because its outermost layer is continuous with the epithelium that lines the ear canal. It protects the middle ear from contamination by foreign material. It also aids in transmission of sound into the middle ear by vibrating as sound waves reach it.

The **middle ear** is an air-filled cavity connected directly to the nasopharynx by the eustachian tube. The eustachian tube is normally collapsed, but opens during swallowing, chewing, yawning and moving the jaw. This allows for equalization of air pressure on both sides of the eardrum to prevent damages to bones of the middle ear structures. The middle ear contains the ossicles, cartilaginous structures of sound transmission. When moved by the eardrum, these ossicles — the malleus (hammer), incus (anvil) and the staples (stirrup) — amplify and transmit sound waves into the inner ear.

The **inner ear** consists of the cochlea, a snail-shaped spiral tube which is the essential organ of hearing, and the vestibular apparatus. The latter structure is responsible for maintenance of balance and equilibrium.

Common Ear Disorders

Excessive Earwax

Approximately two-thousand sebaceous glands line the outer one-third portion of each ear canal. These glands produce a highly viscous, waxy, repellent substance known as cerumen, or earwax. Earwax is colorless when secreted, but turns brown as it mixes with exfoliated (shed) skin, dirt, and debris from within the ear canal. This brown color and reported acrid odor apparently give the substance its disagreeable appearance.

Cerumen consists of fats, fatty acids, water, pigments, and several other yet unidentified substances. Its consistency (hardness), color, and quantity are unrelated to an individual's age or sex. Consistency is determined by the water content. Color is dependent on the amount of dirt and debris present.

Cerumen serves several important functions. It lubricates the lining of the ear canal and helps remove foreign substances that enter the ear, to protect it from damage. It also possesses mild bactericidal and fungicidal actions.

Cerumen is normally expelled from the ears unnoticed in tiny spheres. This movement is aided by movement of the jaw during chewing and talking. Its removal is automatic and ordinarily does not need any assistance. In fact, mechanical removal by inserting hairpins, matches, and similar objects is one of the major causes of trauma and injury to the ear canal. Studies show that most Americans believe earwax should be mechanically removed.

This removal is occasionally impeded because

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C.E. Course

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the individual's ear canal is too narrow. Excessive hair (tragal hair) within the ear canal, or long, coarse hair (especially in older persons), may trap earwax to enhance the retention of a hardened mass of cerumen. On other (rare) occasions, sebaceous secretions may be excessive and allow accumulation of highly viscous material that resists movement. Insufficient chewing and jaw movement are other causes.

The "evils" of earwax and the public's insistence to get rid of it have no doubt been strengthened over the years by articles and advertising claims. It has been suggested that the presence of earwax implies poor hygiene, that deafness is caused by earwax accumulation, and that hearing loss associated with old age can be reversed by cleaning out the ears.

In a study, over one-hundred persons were asked the leading question (thereby expressing approval), "How do you clean your ears out?" More than half of the respondents indicated they used matches wrapped in cotton, and two used the striking end without cotton. Seven said they preferred hair pins. Another four used cotton-tipped applicators.

Carefully performed, such items may help to remove fluid cerumen. But they do not remove dry cerumen. Various studies have, in fact, reported that as many as 75 to 80 percent of all external otitis conditions are caused by individuals using cotton-tipped applicators and other probing objects to clear the ears of earwax. Trauma to the ear canal with epithelial atrophy can be caused by any instrument, even cotton-tipped applicators, placed into the ear canal. Many times these objects push the wax deep into the ear and impact it even more. Its natural removal is thus made even more difficult.

Earwax Softening Agents. As the name implies, these agents soften and loosen earwax. They are available for purchase without prescriptions. These drug products are not the

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same as **cerumenolytics** (e.g., triethanolamine polypeptide oleate condensate - Cerumenex®) which actually dissolve earwax. They require prescriptions.

Common agents used for softening earwax include olive oil (sweet oil), light mineral oil (baby oil), 3% hydrogen peroxide solution diluted by half with warm water, glycerin, and carbamide peroxide. Hydrogen peroxide is satisfactory for occasional application, but should not be used routinely. If it is left in the ear, it can cause maceration of epithelial tissue lining the ear canal, which then predisposes it to infection. Representative OTC products for softening earwax are listed in Table 1.

Carbamide Peroxide (urea hydrogen peroxide). This was the only earwax softening agent that an FDA/OTC advisory panel found to be safe and effective for OTC sale. Carbamide peroxide in anhydrous glycerin has been used as a topical antiseptic for treatment of inflammatory ear conditions since 1946 because it is safe, non-irritating, and non-allergenic. To date, there have been no reports of adverse effects associated with its use.

When it comes into contact with the tissue enzyme catalase, carbamide peroxide releases oxygen. The mechanical action of effervescence from this bubbling oxygen loosens tissue debris and wax, and aids in cleansing the ear canal. There is no proven antimicrobial action that results from this oxygen release.

The FDA advisory panel believed that carbamide peroxide has established efficacy. In one study, twenty-six patients with bilateral excessive or impacted earwax received ten drops of 6.5% carbamide peroxide in anhydrous glycerin in the ears twice daily (morning and bedtime) for six days. This was followed by irrigating the ear canals with lukewarm water twice daily on days five and six. A physician examined the ears on day seven. Complete removal of wax was exhibited in twenty-two patients. Two others required an additional irrigation, which was met with complete success. The remaining two required a second course of treatment at which time the procedure was determined to be successful.

In another study, fifty-seven patients with physician-documented impacted earwax used carbamide peroxide in anhydrous glycerin for three days. This was followed by irrigation with warm water. The treatment was successful in all cases.

The proper procedure for administering ear drops is to tilt the head sideways (affected ear upwards) and place 5 to 10 drops into the ear. The applicator tip should not enter the ear canal or touch any part of the ear. The drops should remain in the ear for several minutes by keeping the head tilted or by inserting cotton. If cotton is used, it should be inserted gently and not packed too far into the ear canal.

Irrigation is not usually necessary when carbamide peroxide products are used correctly. As simple as the procedure sounds, not everyone can syringe his own ears. Syringing requires considerable caution and dexterity. The FDA advisory panel believed that placing an irrigating syringe in the ear should not be done more often than absolutely necessary. Therefore, it suggested that directions for use of carbamide peroxide be

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TABLE 1
Representative OTC Products for Softening Earwax

Product	Manufacturer	Ingredients
Auro Ear Drops	Commerce	Carbamide peroxide 6.5%, in propylene glycol
Aurocaine Ear Drops	Republic	Carbamide, glycerin, and propylene glycol
Debrox Drops	Marion	Carbamide peroxide 6.5%, in anhydrous glycerin
E-R-O Ear Drops	Scherer	Glycerin 95%, in propylene glycol
Kerid Ear Drops	Blair	Glycerin 30%, urea 0.1% in propylene glycol
Mollifene Ear Drops	Pfeiffer	Camphor, cajuput oil, eucalyptus oil, thyme oil, in glycerin
Murine Ear Drops	Abbott	Carbamide peroxide 6.5%, in anhydrous glycerin

C.E. Course

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expanded to state: "Use twice daily for up to 4 days if needed, or as directed by a doctor. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb syringe."

Earwax that remains after four days of self-therapy could signal a serious medical problem and a physician should be consulted. Thus, there is an additional warning: "Do not use for more than 4 days; if excessive earwax remains after use of this product, consult a doctor."

Products containing carbamide peroxide are safe for relieving symptoms of fullness due to accumulated, but not impacted, earwax, ear noises (tinnitus) and dizziness may suggest a more serious disease which requires a physician's attention. To remove impacted earwax, a cerumenolytic agent (none available OTC) or intervention by a physician may be required.

Glycerin. This old-time remedy has been used alone and in combination with other agents for more than a century as a softening agent for earwax. However, there have never been any well controlled studies to establish its effectiveness as a topical earwax softening agent. The FDA/OTC advisory panel which reviewed it suggested that the lack of scientifically valid trials for glycerin is more than offset by its century of widespread clincial use and marketing experience. It is also safe and nonsensitizing when used on abraded skin. The panel, therefore, recommended that glycerin be considered a safe and effective earwax softening agent.

However, FDA disagreed with this. The agency stated that ". . . the existing evidence are not adequate to support the effectiveness of glycerin as an earwax removal aid." Because glycerin still needs additional evaluation before it can be used alone to soften earwax, FDA placed it in the "needs more study" category. Anhydrous glycerin can continue to be used as a vehicle for carbamide peroxide.

Boils

Boils (furuncles) are localized infections of hair follicles. They are usually caused by *Staphylococcus aureus* and are self-limiting. Boils commonly occur on the auricle or within the ear canal beginning as inflamed, red papules (hardened solid mass), but soon pustules appear in their place. Over the next several days to two weeks, these gradually enlarge and open spontaneously, releasing their yellowish contents.

Boils may be extremely painful due to the reasons explained earlier in this lesson. Boils located within the ear canal will cause pain that is exacerbated by chewing.

A boil should not be squeezed or pinched open. This may cause the infection to spread by forcing pus into adjacent tissue or even into the blood. Warm compresses can be applied several times daily to hasten the boil coming to a head. Once this occurs, the discharged fluid should be carefully removed, and the surrounding area cleansed. While topical antibiotics will not effectively treat an infection, an antibiotic ointment can be applied to help prevent invasion by secondary infective organisms. This should be applied after the boil is erupted.

Fungal Infections

Fungal infections (otomycoses) are more often encountered by persons residing in warm, moist climates than those living in colder climates. Candida and Aspergillus species are the usual causes.

Patients with fungal infections will report generalized and persistent itching, irritation, and a sense of fullness in the ear. Pain is usually absent except in severe infections. If present, it will be increased by chewing or yawning. The exudate from the infection is colorless and, when excessive, may block the ear canal.

Diabetics and persons taking broad spectrum antibiotics are more prone to otic fungal infections than others. Diabetics are more susceptible because their circulation to the area is generally poor, and antibiotics may suppress the normal bacterial flora. This predisposes the individual to superinfection by fungal organisms.

Foreign Objects in the Ear

Young children often place small objects or bits of food into their ears. Physicians regularly report removing peas and beans, seeds, rocks and paper wads. Foreign objects in the ear are often relatively painless. The only clue to their presence may be a child's persistent pulling on the auricle, or impeded hearing. Insects may also enter the ear, becoming trapped within the canal or imbedded in earwax.

Unless the foreign object can be easily grasped with the fingers, no attempt should be made to remove it. This is best left to a physician. Insects within the ear canal can often be coaxed out by shining a light beam in the ear. If this doesn't

work, the ear cavity can be filled with mineral or olive oil to drown the invader, and syringed with water 5 to 10 minutes later to remove the insect.

Barotitis (Baro-otitis)

This is a condition encountered by persons descending from high altitudes. It is more common when persons have inflamed sinuses or congestion resulting from an allergy or head cold.

Recall that the eustachian tube is normally closed. As the individual descends to a lower altitude (greater barometric pressure), the tube opens to allow for pressure within the middle ear to equalize the pressure outside the ear. However, at times, the tube fails to respond. This results in a negative pressure within the middle ear. The eardrum retracts, causing severe pain.

The condition is usually bilateral, although it may occur in only one ear. It is more prevalent during periods of congestion when mucus may cohesively bond the eustachian tube together, or physically occlude the tube's lumen. The result is that, as the individual descends, pressure within the middle ear increases more and more. This causes intense pain that may be felt along the entire side of the face and radiate across the back of the head and down the neck.

The condition is often relieved by chewing, yawning, or rotating the jaw. As pain relief is experienced, holding the jaw in that exact position for a few seconds usually allows for complete pressure equalization. Holding the mouth and nose shut while trying to blow outward also helps.

Persons who must fly while they are severely congested can be advised to take a systemic decongestant. This should ideally be started the day before the flight. A topical nasal decongestant instilled 10 to 15 minutes before descent may reduce the severity of discomfort.

If the discomfort persists after these measures have been employed, an OTC analgesic may be helpful to reduce pain. Warm compresses placed over the ear, and sides and back of the neck often help the eustachian tubes open.

Drainage/Discharge

A discharge from the ear may be watery (serous), bloody, or contain pus (purulent). Any trauma to the ear or head may cause exudation of a pus-laden fluid. Self treatment of otic drainage from any cause should be contacted as soon as possible.

Swimmer's Ear

Swimmer's ear (acute edematous otitis externa, acute otitis media, "hot weather ear") is discussed more thoroughly in another lesson in this SCOPE series entitled, "Advising Consumers on Swimmer's Ear." It is briefly described here to make this month's lesson complete.

Swimmer's ear occurs predominantly during the hot summer months. It may also appear following frequent showering, or immersion in bath water, and is more common in individuals residing in hot, humid climates.

The condition may appear whenever extraneous moisture enters the ear canal. Earwax softens and swells. If foreign debris or bacteria enter the ear canal at this point and become trapped in this waxy mass, and the individual scratches or rubs the ear, damage to the ear canal with localized infection may result. The outcome is intense itching and pain in the ear canal.

Swimmer's ear is treated with antibiotics and anti-inflammatory otic preparations under a physician's direction. It can be effectively prevented, however, by remedies intended for self-treatment that dry the ear canal. Such items include extemporaneously prepared solutions of acetic acid 2 to 5% in alcohol, propylene glycol or anhydrous glycerin. A variety of OTC proprietary products is also available.

Overview

Most disorders of the ear are mild and do not pose major problems. However, even mild pain and itching can be symptoms of serious disorders. To continue to treat these symptoms without seeking their cause may lead to irreversible harm to the ear, or worsening of the primary condition. Any symptom that persists beyond two days or worsens even though it is being self-treated should be referred to a physician. It is also important for the pharmacist to distinguish between conditions where OTC treatment is indicated and those where an OTC item should be avoided and the patient referred to a physician.

CE TEST ON PAGE 29

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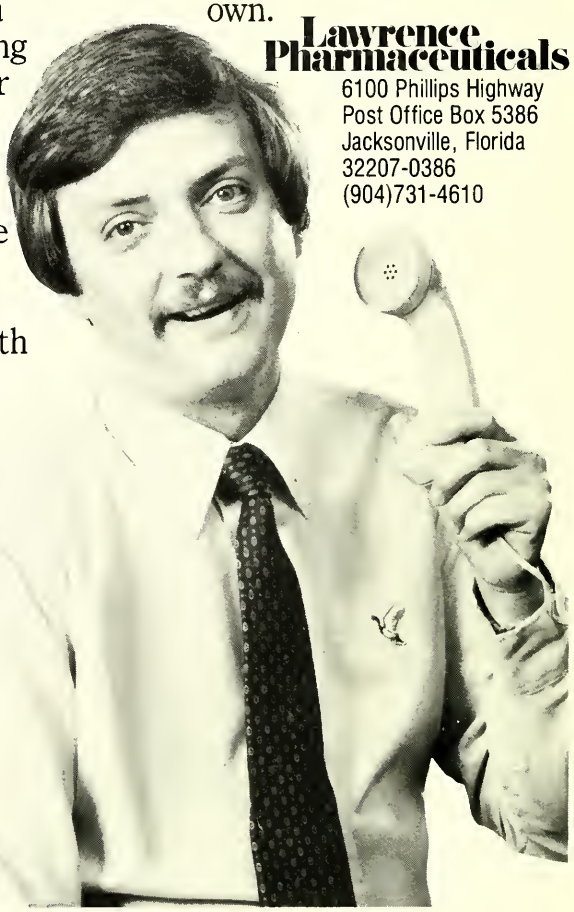

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DICKINSON'S PHARMACY

by Jim Dickinson

Fightin' Pharmacists. Sounds like an old John Wayne movie, but it's far from make-believe.

Pharmacists *are* fighting back, at long last, through PACs, PSAOs, all kinds of co-op buying groups, and now the California Pharmacists Association's PCN ("Pharmaceutical Care Network") that cuts generic drug prices while contracting through wholesalers. And pharmacists are fighting back in the streets, too, through what Oregon State University pharmacy administration professor Lee R. Strandberg calls "Entrepreneurialism in Pharmacy — The New Wave."

These fight-back tactics are unstoppable, can only grow, and are even showing themselves on a nationwide basis through the National Association of Retail Druggists' network for multi-state PSAOs ("pharmacy services administrative organizations").

To put it bluntly, pharmacists have had a gutful, and they're not going to take it any more.

"It," of course, is all the put-downs and exploitation that their placid, agreeable personalities have invited over the years from third-party programs, government payors, manufacturers, media critics, and others, even while that same docility was boosting their ratings in the public's most-respected-professionals' list.

Why has everything changed so suddenly?

Well, first of all, it hasn't been sudden at all. Pharmacist docility has a long history, going all the way back to the 1940s "therapeutic revolution" that mass-marketed new, ready-prepared dosage forms and spelled the end of extemporaneous dispensing. It was a wonderful convenience, fully in keeping with the new labor-saving household appliances and gadgets of the same era, that helped make housekeeping such a bore and create the "working mother."

But the new medicines made pharmacists feel useless, accelerated the advance of self-service drug chains, and inadvertently bred a poor self-image among "count-n-pour, lick-n-stick" pharmacists.

Now, one thing about getting a poor self-image is that it's catching. The detailmen began finding that many pharmacists were pushovers, and so did other sellers. Chains got sassier, stores began to fold, and the pharmacist felt more of a patsy than ever.

In the sixties, along came Medicaid, and prescription paperwork got to be the biggest blight in the profession after chain competition.

Generic drug substitution gave detailmen more opportunities to beat on pharmacists, cyclical economic recessions and deep-discounting dug their own boots into pharmacy's side . . . and along came MAC-EAC, and third-party programs took up that idea, as well.

There's no future for independent retail pharmacy, everyone began saying. The schools were teaching non-entrepreneurial, science-based drug-information and counseling roles, saying that if pharmacy still had a business side, their graduates could learn it out on the streets, later.

So why has all that changed?

It hasn't, yet — but it is changing. Here are some of the reasons:

(1) Manufacturers are worried about market concentration, and don't relish the thought that soon, if the previous trends had continued, they'd only have a handful of national chains and HMOs to sell to. So they've been boosting independent retailing again, helping fund student-motivation programs and other marketplace mechanisms that try to increase the number of units they can sell to.

(2) Americans are getting older faster, and younger slower. That makes them smarter buyers, and ends their love-affair with automated self-service in discount stores. They want to pay for service, and the fastest-growing retailers are those that sell service. Most often, that means smaller stores — the kind an individual entrepreneur can afford to operate.

(3) Health care cost-containment is here for keeps. That makes generic drugs more important and, because of product price competitiveness, freedom-of-choice issues and other decisions the patient must consequently make, the pharmacist more important also. "Count-n-pour, lick-n-stick" is gone forever.

(4) Colleges are running out of kids to teach, so they've got to start re-teaching adults. That coincides with a real need for pharmacists to pick up new skills, especially entrepreneurship related ones, and some schools are trying to offer those; more and more will succeed at this, out of sheer economic necessity.

(Continued on page 28)

Dickinson's Pharmacy

Continued from page 27

(5) There's a product-liability/medical malpractice insurance crisis in the country that makes everyone in the health care business more vulnerable. That will be solved by legislation and tort law reform eventually, but in the meantime knowledgeable pharmacists are both under unprecedented legal pressure and more valuable to society than ever.

All this adds up to an effective antidote to a poor self-image. Polls saying the public thinks pharmacists are wonderful, even if other entities don't, have been a big help.

So now, pharmacists are fighting back, at last. Everybody look out!

This feature is presented on a grant from Mylan Pharmaceuticals, in the interests of promoting the open discussion of professional issues in pharmacy. Mylan Pharmaceuticals accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of Mylan Pharmaceuticals.

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CORRESPONDENCE COURSE QUIZ

Common Ear Disorders

1. The term *pinna* is synonymous with:
   a. auricle.
   b. incus.
   c. malleus.
   d. stapes.

2. The snail-shaped spiral tube located in the inner ear that is the essential organ for hearing is the:
   a. auricle.
   b. eustachian.
   c. cochlea.
   d. tympanic.

3. Which of the following, if any, is/are considered to be safe and effective for OTC sale?
   a. Cerumenolytic agents
   b. Earwax softening agents
   c. Both a and b
   d. Neither a nor b

4. All of the following are proper points of consumer counseling advice regarding carbamide peroxide EXCEPT:
   a. Tilt the head sideways with affected ear upward when applying the drops.
   b. Place 5-10 drops of medication into the ear canal.
   c. Keep the drops in the ear for several minutes.
   d. Irrigate the ear as soon afterwards as possible.

5. Furuncles are usually caused by which of the following organisms?
   a. Aspergillus
   b. Candida
   c. Pseudomonas
   d. Staphylococcus

6. The painful sensation caused by descending from high altitudes too quickly is called:
   a. barotitis.
   b. otitis interna.
   c. tympanitis.
   d. otitis media.

7. The above condition (in #6) is caused by improper opening of the:
   a. auditory canal.
   b. cochlear canal.
   c. auricular tube.
   d. eustachian tube.

8. The glands most responsible for the production of earwax are the:
   a. cochlear.
   b. apocrine.
   c. sebaceous.
   d. tympanic.

9. Sweet oil is a synonym for:
   a. glycerin.
   b. honey.
   c. mineral oil.
   d. olive oil.

10. The enzyme that catalyzes the conversion of carbamide peroxide to oxygen is:
    a. carbamidase.
    b. catalase.
    c. oxygenase.
    d. peroxidase.

11. Carbamide peroxide is safe and effective for relieving the symptoms of fullness due to which of the following conditions, if any?
    a. Accumulated earwax
    b. Impacted earwax
    c. Both a and b
    d. Neither a nor b

12. The membrane that separates the outer ear from the middle ear is the:
    a. auricular.
    b. cerumenic.
    c. otic.
    d. tympanic.

13. Cerumen serves all of the following functions EXCEPT:
    a. exerts mild antibacterial action.
    b. stabilizes the position of the eardrum.
    c. helps remove foreign substances.
    d. lubricates the lining of the ear canal.

14. The action of carbamide peroxide which is documented by the LEAST amount of proven effectiveness is:
    a. aiding in cleansing the ear canal.
    b. softening earwax.
    c. exerting a mild antimicrobial action.
    d. loosening tissue debris.

15. The best type of glycerin to use as a vehicle for carbamide peroxide, or as an earwax softening agent is the:
    a. anhydrous form.
    b. hydrated form.

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Common Ear Disorders

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3. a b c d	*6. a b c d*	*9. a b c d*	*12. a b c d*	*15. a b c d*

Evaluation ☐ Excellent ☐ Good ☐ Fair ☐ Poor

How long did it take you to read the article and complete the exam? _____

MAIL ORDER AND HEALTH CARE COSTS

3-14-86

Mr William Klopman
% Burlington Industries
3330 Friendly Ave.
Greensboro, N. C.

Dear Mr Klopman:

May I take just a minute to express my opinion of your company's new policy of asking your employees to bypass their local pharmacist and to buy their prescriptions from a mail-order company?

There are a lot of options available in covering prescription drugs as a fringe benefit, but this is the worst one that I've seen . . . your brochure tells the employee to just use his local pharmacist for emergencies, and to order his prescriptions three weeks in advance.

I have supported very strongly the limitation of textile imports, and have written to the President as well as Howard Coble and Jesse Helms. I try to buy domestic textile products whenever possible . . . not just on an emergency basis. However, it hurts to see the people that I support doing something like this to hurt my business, as well as all the other pharmacists in the state who have B-I employees as customers.

In other words, we're all sailing in the same boat.

I realize this is the sort of thing that is decided by somebody way down on the corporate ladder, but did not know whom to address about the problem.

I feel sure that B-I could work out a fair and reasonable agreement with the pharmacists of North Carolina that would cost your company no more money, and that would be a great convenience to your employees, many of whom do not like this new policy.

If I can do anything to help correct the situation, please let me know.

Sincerely,
Joe Barbour
Burlington, NC

April, 1986

April 7, 1986

Mr. Joe Barbour
Barbour Drugs
2213 Edgewood Avenue
Burlington, NC 27215

Dear Mr. Barbour:

Your letter of concern about drug prescription services has been referred to me for response.

We do appreciate your concern and your continued support of the company and the textile industry.

As you know, most employers, public and private, have been very concerned for sometime about the upward cost of medical care and drug prescriptions. In fact, the situation has created a set of circumstances that dictates changes within the system.

As a large purchaser of care and services, our company is groping for ways to improve the situation and yet assure that medically needed care and prescription drugs are available at a reasonable price for our family of consumers. I'm sure you fully appreciate the concerns as you no doubt provide services to your employees and, as a commissioner for Alamance County, public employees.

We are not locked into the present system. In fact, this system was created as a first effort to get a handle on the drug purchase question. Under our old reimbursement plan, drugs were allowed as an item in satisfying the deductibles in the package. Therefore, we did not know what the total cost of drugs were nor did we have much information on who prescribes drugs, who needs them, where purchased and how much paid for the drugs. Therefore, a plan was conceived and put in place. We recognize it has some problems and will be working to make changes that will be more appropriate for all concerned in the future.

We estimate that after the first year, we will have enough basic information that will enable us to be better managers. We are certain to develop a more effective and efficient system to meet needed goals.

Thanks again for your concern. We appreciate your willingness to comment. We will place your note in our file so we can consider your ideas when the appropriate time comes for review and a new plan.

Respectfully
Calvin A. Michaels
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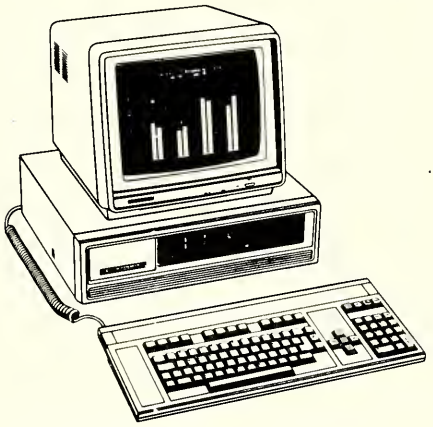

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SEX AND THE DIABETIC PATIENT

by Richard Green, M.D.
Professor, Departments of Psychiatry and Behavioral Science and Psychology
State University of New York at Stony Brook School of Medicine

When David W. began to have sexual problems, it never occurred to him that his diabetes might be involved. He assumed it was all in his head. He had just remarried at age 56 and was still disturbed over the death of his first wife. In time, he would get over it, he thought.

But a year later, his condition was worse. He consulted a urologist who specializes in sexual problems. After a series of tests, the physician confirmed that the patient's impotence was due to diabetes. One complication of the illness, the urologist explained, is small blood vessel disease. In David's case, the arteries were clogged that normally allow the tremendous blood rush to the penis needed to produce adequate erections.

Impotence — Often Not Mentioned

Impotence is one of the most prevalent and yet least talked about complications of diabetes. Compared with some of the other complications, such as heart attack and stroke, it may seem insignificant. But where quality of life and human relationships are concerned, it's crucial.

It is also one of the most insidious complications. While the man's libido continues to respond to erotic thoughts and fantasies, and his genitals remain sensitive to stimulation, he progressively loses his ability to have erections, until the condition becomes permanent.

It is not uncommon for the victim never to mention the sexual side effect to his doctor. But today, more than ever before, there are sound reasons for speaking up. Research has come a long way in determining the precise mechanism of diabetes-related impotence. New advances in diagnostic tests are better able to separate the physical from the psychological components. The net result is that now there is hope even when sexual functionng has ceased entirely.

Diabetes: The Most Common Physical Cause of Impotence

Diabetes has been called the most common medical cause of erectile failure. It is estimated that among people under age 50 with diabetes, more than one-third suffer some degree of impotence. Sexual dysfunction may be the first sign of diabetes. In such cases, not only is the disease present, but it is already producing complications. One study found that over one-third of the men whose impotence was initially attributed to psychological causes actually had abnormal glucose tolerance tests, a laboratory sign of incipient diabetes. And the American Diabetes Association estimates that some five million Americans have undiagnosed diabetes.

It's hardly surprising that sexual dysfunction is more common in diabetic men than in others of the same age. Many of the bodily changes that often accompany the progression of diabetes are the same as those that characterize the aging process. Fatty deposits in the walls of blood vessels and damage to the peripheral nervous system are indicative of both diabetes and aging. In a sense, diabetes simply accelerates the process.

Contrary to expectation, the type and duration of the diabetes, and how well the disease is controlled, do not seem to correlate exactly with the extent of the sexual dysfunction. Some patients experience sexual problems soon after diabetes is diagnosed (or even before). Others go for years before they have any sexual symptoms. Still others experience no dysfunction at all.

A 200-Year-Old Secret

That diabetes is associated with impotence has been known since at least 1798, when an astute English physician published the first report of a case. But it has been only over the past 25 years that the association has been documented in large-scale surveys.

There is still controversy about the precise basis of the dysfunction. At first, it was believed to be principally a consequence of *diabetic neuropathy,* the gradual process of microscopic damage to peripheral nerve tissue. Later, the vascular explanation, damage to blood vessels, gained credibility. The truth seems to lie somewhere between the two. Both an intact nervous system and a healthy blood supply are required for sexual arousal.

(Continued on page 34)

Sex and the Diabetic Patient

Continued from page 33

Women Also Vulnerable

If diabetes produces sexual dysfunction among men, it makes perfect sense that there is a comparable problem among women. Since it is the arousal phase of the sexual response that is affected in men — namely erection — one would expect that women with diabetes would experience less vaginal lubrication. But it is much harder to prove. For whatever reasons, fewer diabetic women complain of sexual problems and studies are contradictory.

Perhaps the greatest obstacle to a definitive answer is cultural. There is not the same stigma. The man who doesn't get erections is obvious. But the woman who doesn't lubricate may still function sexually.

According to one study, women with diabetes do report less lubrication than non-diabetic women. And there were more complaints of pain or discomfort during intercourse from the diabetic group. This might be caused by decreased lubrication or the higher incidence of vaginal infections among diabetic females.

The Body-Mind Connection

Just because a diabetic man suffers from impotence does not mean that his diabetes is the cause. People with diabetes are vulnerable to all the physical and psychological infirmities that play on anyone else. Plus one more. The diabetic male who knows that his disease is associated with impotence may psych himself into failure — creating a self-fulfilling prophecy. He may become so fraught with worry that performance anxiety inhibits his sexual functioning.

All of this interplay considerably complicates determining the cause of impotence in a diabetic person. How much is physical and how much psychological is often difficult to resolve. That's why any man with diabetes who complains about lack of erections needs a specialized, comprehensive work-up.

"Talk Therapy"

Once the cause of impotence has been diagnosed, treatment can proceed. Approaches range from "talk therapy" to penile implants — the surgical implantation into the penis of a pair of semi-rigid or malleable rods or hollow, inflatable cylinders.

When the impotence is partly or entirely psychological, sex therapy is the first course of treatment. If the man is married, the couple should be treated together, although individual therapy can also be helpful.

Artificial Erections

When the cause of the impotence is physical or a mixture of physical and psychological that doesn't respond to sex therapy, an operation to insert a penile implant may be desirable. If the man has a sexual partner, she should be involved in the decision-making process. This surgery has been performed for nearly 20 years. It has been estimated that more than 40,000 men have had penile implants. Artificially created erections seem to be the best available solution for the impotent diabetic male who does not want to give up sexual expression through intercourse.

Today, diabetic men who develop sexual dysfunction are at a considerable advantage over males in the past for whom little could be done. Major advances in the management and understanding of diabetes, impotence and the interplay between the two offer the diabetic male effective management of the situation.

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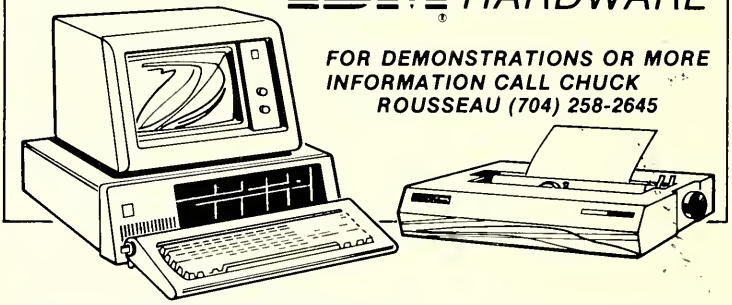

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THE CAROLINA
JOURNAL of PHARMACY

MAY 1986 VOLUME 66 NUMBER 5

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Newly installed officers of the North Carolina Pharmaceutical Association are: First row —Claude U. Paoloni, Member at Large; M. Keith Fearing, Jr., President; Julian E. Upchurch, First Vice President; Albert F. Lockamy, Jr., Second Vice President. Back row — W. Robert Bizzell, Third Vice President; Pamela U. Joyner, and Joseph A. Edwards, Jr. Members at Large.

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COMMITTEE REPORT OF THE COMMITTEE ON ETHICS, PRACTICE AND GRIEVANCE

106th ANNUAL CONVENTION OF THE NORTH CAROLINA PHARMACEUTICAL ASSOCIATION

APRIL 20-22, 1986 HOLIDAY INN FOUR SEASONS GREENSBORO

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Evelyn P. Lloyd, Hillsborough
Albert F. Lockamy, Jr., Raleigh
A. Wayne Pittman, Chapel Hill
Billy L. Price, Jr., Conover
Alicia J. Thompson, Greensboro

With the 1985 adoption of the revised Constitution and Bylaws of the North Carolina Pharmaceutical Association, the Ethics, Practice and Grievance Committee was established as one of the Association's Standing Committees. The purposes, duties and responsibilities are set forth in Article III, Sections I, II and III of the Constitution. Section I reads:

> "Code of Professional Ethics: The Association shall adopt a Code of Professional Ethics, the purpose of which is to elevate the standards of the professional practice of pharmacy and serve as a guide for the conduct and application of professional judgement by pharmacy practitioners. All applicants for active membership shall subscribe to the Association's Code of Professional Ethics and continue to do so upon renewal of membership"

This is exactly what your Committee set out to do this year — develop a Code of Professional Ethics.

Before our first meeting every state pharmaceutical association was solicited for a copy of their own Code of Ethics. Out of twenty-seven respondents, thirteen sent copies of their codes which varied in breadth and depth of contents; ten patterned theirs after the APhA Code of Ethics, and four indicated they had none. Members were assigned to review the APhA Code along with two different state codes in preparation for our first meeting on December 1, 1985.

At this meeting members identified issues that should be addressed by the Code. These included:

- — the patient's interest should always be placed first;
- — the importance of continuing education for competent pharmacists;
- — fair and reasonable purchasing and pricing practices that place value on the pharmacists' time, education and knowledge in perspective.
- — issues that have been identified through resolutions passed by previous conventions;
- — the importance of the pharmacist-patient relationship, discouraging mail-order pharmacy practice;
- — impaired pharmacists;
- — the document should be directed toward individual pharmacists rather than pharmacies

Also, the Committee agreed the APhA Code of Ethics was the type of document we would like

continued on page 6

Photo by Colorcraft

Claude Paoloni, Chairman

Ethics Practice and Grievance

continued from page 5

to use as a guide in developing our own for the Association. Toward this end, a subcommittee of Wayne Pittman, Al Lockamy and Evelyn Lloyd was appointed to develop a proposed Code based upon the discussion that took place at our first meeting. This subcommittee presented a first draft which was distributed to the Committee members on February 13th. A second draft followed on February 18th; third draft on March 3rd and finally the fourth draft went out on March 12th. At the March 23rd meeting the Committee recommended the enclosed code; The Proposed Code of Professional Ethics of the North Carolina Pharmaceutical Association, for adoption by the Association for the self-governance of its members.

Mr. Chairman, this report is respectfully submitted. On behalf of the Committee, I move the adoption of this report.

For the Committee,
Claude U. Paoloni, Chairman

Jean Morse, outgoing Woman's Auxiliary President, putting the President's pin on Jewel Oxendine, incoming President.

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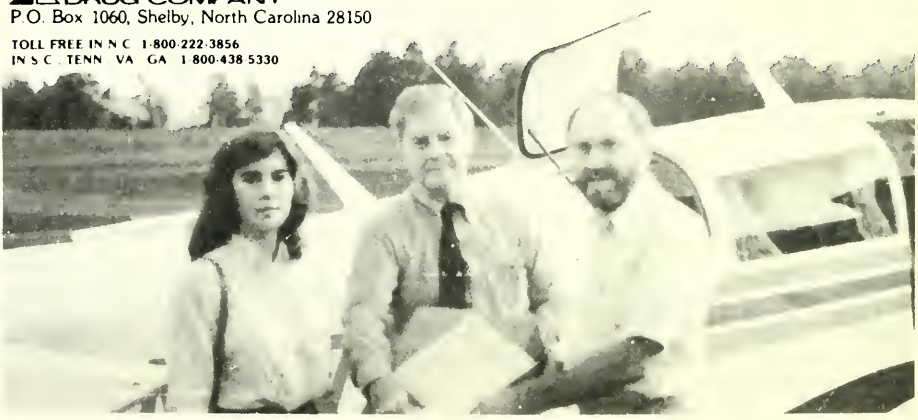

PROPOSED CODE OF PROFESSIONAL ETHICS OF THE NORTH CAROLINA PHARMACEUTICAL ASSOCIATION

A Statement of Principles of Professional Conduct Recommended to the Association for the Self-Governance of its Members

PREAMBLE

Pharmacists possess a unique and specialized body of knowledge that together with their skill and competency must be maintained. In order to serve the public health and welfare, law is established to restrict the practice of Pharmacy to persons with special education and training whose qualifications and demonstrated competency grant them license and privilege denied to others. Because a profession requires its practitioners to consider the needs of its patients paramount, a basic and fundamental component is an unselfish concern for the welfare of others. Accordingly, Pharmacists recognize their responsibility to the community they serve to foster its well-being and to fulfill their professional obligations with honor and integrity.

These principles of professional conduct for Pharmacists are therefore established to guide relationships with patients, the public, fellow practitioners, and other health professionals.

CODE OF PROFESSIONAL CONDUCT

SECTION 1

Pharmacists should hold the health and safety of patients to be of first consideration; they should render to each patient the full measure of their ability as an essential health care provider.

SECTION 2

Pharmacists should provide medication, medical devices and accessories that are safe and effective and that meet recognized standards of quality. They should never condone, support, nor assist in the distribution of any drug or drug paraphernalia used to facilitate, or intended or designed to facilitate, violation of law.

SECTION 3

Pharmacists should always strive to enhance, broaden and perfect their professional knowledge and information necessary to apply to the delivery of their professional services.

SECTION 4

Pharmacists have the duty to observe the law, to uphold the dignity and honor of the profession, and to accept its ethical principles. They should not engage in any activity that will bring discredit to the profession and should expose, without fear or favor, illegal or unethical conduct in the profession.

SECTION 5

Pharmacists should neither agree to nor practice under terms or conditions which tend to interfere with or impair the proper exercise of their professional judgment and skill, which tend to cause a deterioration of the quality of their service or which require them to consent to unethical conduct.

SECTION 6

Pharmacists should provide complete and accurate information to patients regarding professional services and should not misrepresent the quality, cost or value of those or related services.

SECTION 7

Pharmacists should seek at all times only fair and reasonable remuneration for their services. They should never agree to, or participate in, transactions with practitioners of other health professions or any other person under which fees are divided or which may cause financial or other exploitation associated with the rendering of their professional services.

SECTION 8

Pharmacists should respect and honor the confidential and personal nature of patient-related information and associated professional records; except where the best interest of the patient requires or law demands, they must not disclose such information to anyone without proper authorization.

SECTION 9

Pharmacists should associate with professional organizations having for their objective the protection of the public health and welfare and the betterment of Pharmacy. They should contribute of their time and resources to carry on the work of these organizations.

Adopted by the North Carolina Pharmaceutical Association in convention assembled April 22, 1986

ADDIE PEGRAM

Addie Lee Bradshaw had no idea she was making history when she stepped off the train at the University of North Carolina at Chapel Hill in 1920.

The 20-year-old Lenoir native was just worried about finding her way around the university town and the pharmacy school located right in the middle of campus.

Today, Addie Lee Pegram, 85, laughs when she recalls the scared young woman who rode the train full of boys from Hickory to Chapel Hill. She admits she had no idea she would be the first woman to receive a pharmaceutical degree from the university.

"There were 57 people in my graduating class in 1922—56 men and me," Mrs. Pegram said recently at her Cary home. "There had been some girls before me and none had ever graduated. If I had known how difficult it was going to be, I probably would have stayed home, too."

Mrs. Pegram has lived in Cary's MacGregor Downs for about six years with one of her four daughters, Jean Fitchett. Mrs. Pegram retired in 1965 as the pharmacist and owner of Pegram's Drugstore in Apex.

In 1972, she received her 50-year pin from the N.C. Pharmaceutical Association, being the first woman pharmacist in the state to earn the award.

Her path to pharmacy school started right after high school in Lenoir, a town located in the foothills of the state.

The local pharmacist, J.G. Ballew, offered her a job at the cosmetics counter in his store.

"It was a thrill for me working at the drugstore. I was making $5 a week and loving it," Mrs. Pegram said. "After about a year, Mr. Ballew told me he thought I would be a good pharmacist and I ought to think about going to school."

But her parents, Julius and Lula Bradshaw, had eight children to raise. Two of her brothers already were attending today's N.C. State University in Raleigh and "my father just felt that girls did not go to college and he knew he had to send my brothers," Mrs. Pegram said. "So I told Mr. Ballew I would have to stay home."

But Ballew was not to be talked out of the plan. He offered to send her to school if she would return and work in his drugstore and pay him back at four percent interest.

"I finally got my father to agree to the plan," Mrs. Pegram said. "And I might add that my other three sisters all ended up going to college."

Loaded with her uncle's trunk and a special lunch made by her mother, the then Addie Bradshaw boarded a special train in Hickory, full of men and bound especially for the university.

A special horse and buggy from the campus YMCA met her at the train station in Carrboro and took her to a boarding house in Chapel Hill. There were no women's dorms on the campus.

"I lived at Mrs. Neville's house and ate all my meals at a large white boarding house near where the Carolina Inn is today," Mrs. Pegram said.

She wasted no time getting involved on campus, becoming a member of the girls basketball team, which could not practice in the gym.

"I also helped form a petition that went to the governor asking for a girl's dorm on campus," she said. "I never was able to live in it, but Spencer dorm was started soon thereafter for women."

The pharmacy school was located then in a small building near the Old Well that now is part of the music school. The majority of the classes were held in Howell Hall, now the journalism school.

"The pharmacy program then was two years and it was very hard," Mrs. Pegram said. "We had labs every afternoon and attended classes in the mornings."

Being the only woman in a school of all men was never a problem, she recalls. "They always were very cordial to me," Mrs. Pegram said.

She only remembers one embarrassing incident: one day in chemistry class, she was standing to answer a question and her red taffeta petticoat fell down around her ankles. "No one laughed or said a word. I just reached down, picked it up and ran out of the room. It wasn't 'til I reached the door that everyone exploded into laughter."

Graduating with honors from UNC in 1922, Mrs. Pegram did return and worked for five years in Ballew's drugstore, paying back her college loan.

A woman pharmacist was basically unheard of in those days, and Mrs. Pegram had her share of problems.

"I remember one man in particular who came in and just refused to let me fill his prescription because I was a woman and Mr. Ballew was not there," she said. "I finally got him to come behind the counter and watch me fill it to show him I did it just like Mr. Ballew. I had a regular customer from then on."

Even though she had been surrounded by UNC men for two years, Mrs. Pegram was introduced to her future husband by one of her

brothers attending N.C. State. She married Calvin Winchester Pegram in 1924. With two young daughters, they moved in 1927 to Virginia when Pegram became a professor in the agriculture department at VPI.

But her days at the UNC Pharmacy School were not over. With four little girls and a husband, she would return 15 years later to work on her bachelor of science degree in the four-year program.

"I remember going to see the dean and he listened to what I wanted to do and told me to go home to my daughters," Mrs. Pegram said. "I had my pharmacy license and all but I told him I loved pharmacy and wanted to learn all I could, so I wanted the bachelor's degree."

The beginning of World War II halted Mrs. Pegram's return to Pharmacy School, one semester away from graduation.

During the war, pharmacists were difficult to find. Living with her family in Raleigh, Mrs. Pegram was asked to fill in at a drugstore in Apex. She went there in 1942 and did not leave until she retired 23 years later.

"I went there to keep the store open, basically, but we ended up buying the drugstore in 1945 when the owner died," she said. "I loved Apex and working with the customers there. It was like one big family."

Today, Mrs. Pegram keeps in touch with the pharmacy profession through Cary resident Susan Ladd, daughter of Dick and Jean Ladd, longtime friends of the Pegram family.

Ms. Ladd, a 1980 graduate of Cary High School, graduated from the UNC Pharmacy School in May 1985.

Addie Pegram was presented her 50+ certificate in 1972 by NCPhA President Tom Burgiss.

The NARD Leadership Award is presented to NCPhA incoming President M. Keith Fearing, Jr. by Jesse M. Pike (right), a past president of NARD, while Mrs. Fearing approves.

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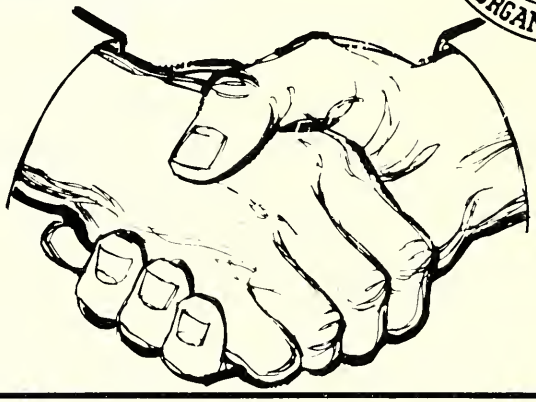

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TMA Officers for 1986–87. Left to right, L.M. McCombs, Sec.-Treas.; Stephen L. Collins, Past President; E. DeLacy Luke, 2nd Vice President; and G. Douglas Sanders, 1st Vice President. (Not pictured — John T. Black, President)

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DICKINSON'S PHARMACY

by Jim Dickinson

Unleashing the nuts. "I'm only afraid that we might have unleashed the average nut out there," said the eminent drug attorney, speaking of SmithKline's bout with Contac, Dietac and Teldrin tampering. This, in his view, was far more menacing than either of the Tylenol episodes which, he thought, reflected a rare mix of psychosis and cunning. SmithKline's tamperer by his unsophisticated sloppiness showed that he probably belonged to the more common, everyday variety of nut.

"That's really frightening," the lawyer said. "Those people even belong to a kind of psychotic network, and they share the same weird, anti-social ideas. They're not your classic 'loner' out there."

Network? I thought of electronic bulletin boards, information exchanges, and *National Kook* magazine with all its classified ads ("Poison whole cities. Send $50 and SAE for secret details . . .")

I also thought of California Pharmacists Association executive vice president Robert C. Johnson's description, at an April conference in New Zealand, of the U.S. health care system as "bizarre, insane." He wasn't talking about tampering, but he might as well have been (he was talking about mail-order RXs and drug company competition with pharmacists in the home health care market).

The "bizarre, insane" fact is that America probably has the least-restrictive OTC drug distribution system in the advanced world, and it certainly has the advanced world's first and only large-scale OTC drug product tampering problem.

The British Pharmaceutical Society (which duplicates as a national pharmacy board) maintains an extensive intelligence center for world drug information and news, and in April it told me that the *only* drug tampering cases it has in its files are the U.S. ones.

I called Leroy Fevang, executive director of the Canadian Pharmaceutical Association, and he said they had had only two "mild" copy-cat cases of tampering that did no harm, after the 1982 original Tylenol tragedy. One involved Metamucil, and the other Drano.

What do these other advanced countries, including Canada, have in common, that we don't?

They have a pharmacist-legend class of drugs. And, even in Canada, their pharmacies tend to be smaller than our super drug discount stores, and pharmacist supervision is easier in smaller stores.

In Australia, the government is thinking about dismantling its long-established pharmacist-legend system for OTCs, and has been looking favorably at the U.S. system as a good example to follow. In this, it has been aided by the proprietary medicines industry, which objects to the advertising ban Australia has on restricted OTCs, and which looks enviously to the added sales opportunities that supermarkets and other non-pharmacy outlets provide for U.S. OTC firms.

To help its arguments, the Australian industry has conducted shopper surveys showing that most pharmacists simply don't do the sales supervising job they're expected to do in the pharmacist-legend category.

But Australia also has no tampering problem. Neither do any of the other sophisticated countries outside the U.S.

Now why do you suppose that is so?

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answer from the opponents of pharmacist-legend. It will be this: "There are deep cultural and societal differences between countries. Comparisons can be misleading and not meaningful."

Except when you're an Australian OTC manufacturer trying to persuade that country to adopt a U.S.-style system! (P.S.: most of the Australian OTC drug firms are branches of U.S. companies!)

APhA as phoenix. I hesitate to write about this again. Everyone tells me that organizational affairs are such a bore. But births are never boring, and at APhA's San Francisco meeting, we saw signs of a healthy rebirth of what had tended to become a moribund organizational democracy.

APhA's House of Delegates, representing the great grassroots of all of American pharmacy, voted to have a firm new say in association affairs from now on, no longer trusting in the "establishment."

With surprisingly little dissent, it decided that APhA must not implement its proposed reorganization plan without house assent (which means back to the drawing-board, and let's look at it again next year). It also decided to democratize APhA elections so that nominees are chosen independently, without leadership clearance first.

And, too late to prevent the walk-out of Academy of Pharmaceutical Sciences members to the new American Association of Pharmaceutical Scientists, it decided that whatever reorganization finally does emerge, it must not eliminate elective subdivision officer posts, a primary beef the scientists had with the pending reorganization.

Cheering, positive developments that help lift APhA out of its post-Apple doldrums!

This feature is presented on a grant from Mylan Pharmaceuticals, in the interests of promoting the open discussion of professional issues in pharmacy. Mylan Pharmaceuticals accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of Mylan Pharmaceuticals.

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GUILFORD COUNTY

The regular monthly meeting of The Guilford County Society of Pharmacists was held Sunday, May 11, 1986 at 8:00 p.m. in the AHEC Auditorium at Moses H. Cone Hospital. Speakers for the evening were Dr. Phillip Buscemi, O.D., of Carolina Eye Care in Greensboro, and Judith Crouch, R.Ph., of the Cone Hospital Pharmacy staff. The topic for the C.E. approved program was "Common Problems and Care of Contact Lens", and the assembled members were treated to a very interesting discussion and gained a great deal of information useful in our pharmacy practices. Following a short business session dealing with plans for a July "Pig Pickin" and a treasurer's report, the meeting was adjourned.

Frank Burton
Sec.-Tres.

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COMMITTEE REPORT OF THE COMMITTEE ON WOMEN IN PHARMACY

106th ANNUAL CONVENTION OF THE NORTH CAROLINA PHARMACEUTICAL ASSOCIATION

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Liason to Executive Committee

The Women in Pharmacy Committee met twice this year — both times in Winston-Salem. With the large number of women entering the profession, we still feel that there is a need for this committee. Current statistics show that of the pharmacists licensed in North Carolina, 70% are male, and 30% are female. While this is a 1% decrease in the percentage of women last year, 64% of the pharmacy students at UNC are women. If this trend continues, the percentage of women practitioners will approach 50% by the year 2000.

The Committee worked on three major projects this year:

1. The Committee would like to determine whether or not the increasing number of women in the profession will have any impact on pharmacy in the future in North Carolina. We have had an on-going project for two years to conduct a survey of pharmacists in the state in order to determine this. For our basic survey, we plan to use Dr. Jean-Paul Gagnon's "NCPhA Employee Survey." Last year the Committee wrote questions to add to the original survey about interest in professional organizations, management opportunity, child care, and discrimination. We hope to determine for this survey that women are no longer "part-time" workers, that they have a desire to become managers, and that they have an interest in running for offices and becoming involved in professional organizations.

The major problem of this project for the Committee is that we have not been able to raise the money to do the survey. Jean-Paul Gagnon estimates that it will cost $2,000 to conduct the survey. We have asked all the major drug companies and have been turned down, so this year we decided to ask the drug wholesalers in the state. As of April 1, 1986, the Committee has been given a total of $150 from W.H. King Drug Co. of Raleigh and Kendall Drug Co. of Shelby. McKesson Drug Co. of Cayce, SC, has offered to help us print the survey at a lower cost than had been estimated. At our last committee meeting, we discussed the possibility of condensing the survey (and thus lowering the cost), and we may consider that option if we cannot raise more money.

2. The Committee is planning to work with Kappa Epsilon to present a panel discussion of different pharmacy career opportunities, besides

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Marilyn McConnell, Chairman

Women in Pharmacy

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the traditional hospital vs. retail. We have been in touch with Laura Dillard, President of Kappa Epsilon, Lambda Chapter, at UNC. Laura thinks that such a discussion would best benefit freshmen or sophomores who are undecided about whether or not to attend pharmacy school, and she recommended that we present this program during fall semester prior to the application deadline for pharmacy school. We plan to hold this panel discussion in either September or October of this year, and if it is successful, we intend to make it an annual event at the School of Pharmacy.

3. The Committee is sponsoring part of one of the workshops at the NCPhA convention this year. The program is entitled "Current Women's Health Issues: Pre-Menstrual Syndrome" and was designed by Kappa Epsilon and Lambda Kappa Sigma Pharmaceutical Fraternities. The speaker will be Elizabeth L. Ayers, Grand Treasurer of Kappa Epsilon.

Pages Teresa Turner and Lois Brooks during a quiet moment at the 1986 Convention.

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CORRESPONDENCE COURSE

ADVISING CONSUMERS ON SWIMMER'S EAR

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University, Ada, OH
and
J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati, Cincinnati, OH

Goals

The goals of this lesson are to:
1. describe the etiology and treatment of swimmer's ear;
2. explain how to advise patients on the proper instillation of otic products.

Objectives

At the completion of this lesson, the successful participant will be able to:
1. show an understanding of how swimmer's ear is contracted;
2. identify the pharmacological action of these otic products;
3. explain the proper technique for instilling otic products;

Disorders of the ear are common complaints of consumers who come into the pharmacy for medications and advice. This lesson will be limited to a discussion of external otitis (inflammation of the outer ear) — swimmer's ear. Although mild, nonchronic swimmer's ear is not self-treatable, it is often preventable.

The term *external otitis* refers to an inflammation of the auricle and external auditory canal. While many factors may cause inflammation of the ear, the most common causes are those that are associated with swimmer's ear.

Occurrence

Swimmer's ear, also called acute edematous otitis externa and "hot weather" ear, predominately occurs during the hot summer months. It usually results from swimming in fresh water streams, lakes and community pools. It rarely occurs from swimming in oceans and salt water rivers.

Frequent showering or immersion in bath water can also cause the condition. Persons living in hot, humid environments develop the condition more often than individuals residing in drier climates, even if they do not go swimming. Blacks are rarely affected; the reason(s) for this is (are) unknown at this time.

Some physicians report that swimmer's ear accounts for up to 20 percent of all patient visits during the summer months. Many of these visits result from persons using foreign objects, i.e., pencils and hair pins, to clean out the ears or relieve itching. This traumatizes the tissues and results in further damage that may require treatment with anti-infective and/or anti-inflammatory agents.

Physiology of the Ear

In order to thoroughly understand how swimmer's ear develops, the anatomy and physiology of the ear canal (Figure 1) should be understood.

The ear canal is a cone-shaped structure approximately one-inch in length from outside to inside, that ends blindly at the tympanic membrane (eardrum). This makes it the only

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in the service of pharmacy

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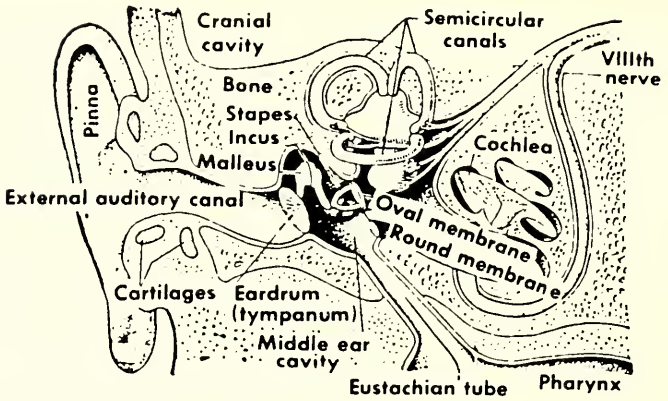

FIGURE 1 Diagram of human ear, lying in petrous portion of temporal bone. (From Storer; General Zoology, McGraw-Hill Book Co., Inc.)

Swimmer's Ear

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epithelial-lined cul-de-sac in the body. It is this same anatomical feature that also makes the ear canal unique. Because the auditory canal points slightly downward and ends blindly, moisture and foreign particles may readily become trapped within it. The canal is also twisted. Therefore, substances that enter are not promptly expelled.

The skin and underlying subcutaneous layer lining the ear canal is thinner than skin elsewhere on the body. This skin is also tightly stretched. Therefore, the slightest inflammation will be interpreted as having much greater intensity than a quantitatively similar inflammatory reaction elsewhere on the body. Pain originating in the tissue anywhere along the external ear may be uncomfortable.

The pH of the epithelium that lines the ear canal is acidic, approximately 6.0. This acid mantle must be maintained in order to preserve a normal healthy ear canal. An acid pH helps guard against microbial penetration and colonization.

Numerous glands line the ear canal and secrete waxy substances which form earwax (cerumen). Earwax is important to the external ear to maintain its normal health and integrity. Basically, earwax lubricates the tissues along the ear canal. Because it is constantly moving outward to be expelled, it aids in the removal of microorganisms and foreign debris. Earwax is also believed to possess bactericidal and possibly fungicidal properties. The precise role that earwax plays in maintaining a healthy ear will be discussed in more detail in the second lesson of this series.

Additional factors that may promote swimmer's ear include narrow ear canals, abundant hair growth within the ear, or excessive cerumen production. All of these elements can impair the ear's natural cleansing process by impeding the outward movement of earwax, and causing entrapment of debris.

Causes of Swimmer's Ear

Any force that irritates the ear canal can potentially result in swimmer's ear. However, the two major predisposing factors are heat and humidity. Whenever extraneous moisture is introduced into the ear canal (such as during hot, humid weather), earwax absorbs it, becomes soft and swells. This softened mass increases the maceration of underlying epithelium, and induces development of minute fissures in the tissue. As tissue maceration progresses, the acid mantle shifts toward alkalinity. The softened wax may eventually wash out as more and more moisture is introduced into the ear canal. Meanwhile, the skin's normal defense barriers are compromised, and conditions are optimal for microbial invasion.

As long as the softened, swollen earwax remains within the ear, other potential complications may arise. For example, sand or dirt particles entering the ear canal may become trapped in this mass. If the area is scratched or rubbed so that the particles scrape the delicate tissue, it may be injured further. The likelihood of this is great because itching is one of the most common symptoms of inflammation and microbial

TABLE 1
Microorganisms Cultivated From Ears of Subjects with Confirmed Swimmer's Ear

Gram-Positive Bacteria
- Bacillus sp.
- Diptheroids
- *Staphylococcus epidermidis*
- *Streptococcus viridans*
- Micrococcus sp.

Gram-Negative Bacteria
- Aeromonas
- *Enterobacter aerogenes*
- *Escherichia coli*
- Herellea
- *Klebsiella pneumoniae*
- Mima
- *Pseudomonas aeruginosa**
- Serratia marcescens

Fungi**
- *Candida albicans*
- Neurospora
- Oospora sp.

**P. aeruginosa* alone, or as part of a mixed culture, was found in over 50% of cases.

***Fungi were found in less than two percent of cases, and ⅔ of these were Candida.

infection. Then the outer layer of skin loses even more of its normal resistance to entry of microorganisms. This results in an even greater chance for infection.

The actual symptoms of swimmer's ear result from microbial invasion and colonization of the epithelial lining which induces a local inflammatory response and edema.

Table 1 lists the microorganisms that have been identified from isolates removed from ears of patients who have experienced swimmer's ear. While each is a potential cause, *Pseudomonas aeruginosa* has been the most commonly encountered microbe. Pseudomonas is not normally found within the human ear canal. Staphylococcus is another prevalent invader. Mixed infections are frequently seen. When isolate cultures are positive for fungus (which is rare), the most common species found is Candida.

What is the Role of Heat and Humidity on the Development of Swimmer's Ear?

Animal studies involving cats have been undertaken to provide an overall understanding of swimmer's ear. It has been shown by these studies that no single factor could cause morphologic or pathologic changes in the lining of the ear. Conditions of high temperature or humidity aggravated the problem caused by other factors. These same conditions, alone or in combination, did not cause inflammatory changes *per se* or worsen the situation caused by the other factors. In all cases, pseudomonal infection was a prerequisite for appearance of symptoms, but this had to be combined with localized trauma or physical damage from improper earwax removal.

Symptoms of Swimmer's Ear

The first noticeable symptom is usually itching which occurs within an hour or so of swimming or getting moisture within the ear. At first, the itching may be tolerable, but it gradually progresses to unrelenting discomfort. An itch-scratch-itch cycle may be initiated as the victim continues to scratch. Therefore, the potential for causing serious traumatic injury to the ear canal with resultant infection is increased.

Shortly after the onset of itching of swimmer's ear, pain and a feeling of fullness in the ear are experienced. Tenderness around the entire ear may be prominent. These sensations are increased by applying pressure to the ear, pulling on the auricle, or moving the jaw by chewing or yawning.

A copious watery (serous) discharge may be detected in severe cases. This fluid eventually becomes pus-laden (seropurulent) as the problem worsens, usually within several days. When the condition continues untreated, hearing may be diminished due to blockade of the ear canal by local edema and swollen earwax.

A bacterial infection of the ear canal may cause even more serious complications. If the infection spreads through the eardrum to the middle ear to cause infection with pus formation, the resulting pressure could cause this membrane to rupture.

Swimmer's ear is usually unilateral. While recurrent infections are common, the condition rarely extends systemically.

Treatment of Swimmer's Ear

In general, swimmer's ear should not be self-treated. There are currently no available OTC products indicated for this purpose. The FDA/OTC advisory panel that reviewed otic

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Swimmer's Ear

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drug products reported that swimmer's ear should only be diagnosed and treated by a physician. However, once the condition has been effectively treated, or for those persons known to be at high risk for developing swimmer's ear, the condition can often be prevented from recurring in the future.

A variety of OTC products are available for this purpose (Table 2). Alternatively, other formulations may be extemporaneously prepared for use in preventing swimmer's ear. Both the OTC products and the extemporaneously prepared mixtures are intended to dry the area and restore proper acidity to the ear canal.

Extraneously Prepared Mixtures. Pharmacists can prepare a 2.0 to 2.5% acetic acid solution in 70% isopropanol or ethanol, propylene glycol or anhydrous glycerin. Distilled white vinegar is acetic acid (5%), and this can be used to prepare the solution when glacial acetic

TABLE 2
Representative OTC Products for Preventing Swimmer's Ear

Product (Manufacturer)	Ingredients
Dri Ear Drops (Pfeiffer)	2.75% boric acid in isopropyl alcohol
Ear Dry Drops (Scherer)	" " " "
Swim-Ear Drops (Fougera)	" " " "
Aurocaine 2 Drops (Republic Drug)	" " " "
Auro-Dri Drops (Commerce)	" " " "
Aqua-Otica-B Drops (Ortega)	Aluminum acetate, boric acid, 1%; acetic acid, 1%, propylene glycol; benzyl alcohol, 0.5%

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acid (99.5%) is not available. Acetic acid helps restore acidity to the tissues lining the ear canal. It also has an anti-itching action. Itching can be further controlled with an alcohol vehicle. Furthermore, the resulting acid/alcohol mixture is antibacterial.

Propylene glycol is a viscous vehicle which increases the contact time of acetic acid on the epithelium. Anhydrous glycerin will help remove moisture from within the ear canal. However, it has no activity on moisture contained in intact epithelium.

A solution of boric acid, 2 to 5% in ethanol or propylene glycol, has also been recommended to restore acidity in the ear. But boric acid may be toxic if it is absorbed across broken skin or accidentally swallowed. For this reason, it should not be used if acetic acid is available.

Several years ago, a study reported on the prophylactic use of a 2% acetic acid solution in the ears of children, aged 9 to 14 years, visiting a summer camp. The camp's swimming pool was too small for the large number of campers who used it, and these youngsters traditionally experienced a high incidence of swimmer's ear each summer.

The children were placed into either a control group or a treatment group. Each morning and evening two drops of ear solution were placed in both ears of persons in the treatment group. The children in the control group received no medication. The study continued over two summers. Test results were as follows:

At the end of the first year, 2/246 treated, versus 10/246 non-treated youngsters developed swimmer's ear. By the end of the second year, 4/221 treated, versus 14/202 non-treated children developed the condition during their camping vacation. It was concluded that treatment with acetic acid caused a statistically significant reduction in occurrence of swimmer's ear.

Consumer's Advice

Consumers who are plagued with swimmer's ear may have numerous questions about the disorder. Many will seek a pharmacist's counsel before visiting a physician. It is important that pharmacists have the proper information about the condition, and that they discuss it with those persons. Furthermore, pharmacists should not hesitate to recommend that a patient displaying persistent or overly bothersome symptoms of swimmer's ear see a physician as quickly as possible. Without this counsel, patients may be tempted to use unfounded remedies, or to improperly use an OTC product. While this may bring about temporary, symptomatic relief, it may also cause further damage to the ear.

Consumers should be advised that swimmer's ear is *not* to be self-treated. Symptoms such as pain, itching, and inflammation are general enough that they may represent many other disorders. The appearance of symptoms is not an automatic indication for using OTC otic products. As stated, the OTC products are indicated for prevention, not for treatment.

Individuals with swimmer's ear who seek a physician's advice will probably receive a prescription for an otic antibiotic or steroid/antibiotic combination product to treat the condition. Individuals with a history of swimmer's ear may be given a prescription for an item such as Vosol Otic solution (2% acetic acid in propylene glycol) or be advised to purchase one of the OTC products, or a suitable extemporaneously prepared solution.

It is important that pharmacists counsel patients on the proper use of otic products. Extreme care should be exercised to avoid contamination of the dropper or bottle tip. When instilling the drops, the patient should hold his head to one side, with the affected ear upward. The auricle should then be grasped and pulled to straighten the ear canal as explained in Figure 2.

Inserting a cotton "wick" in the ear is somewhat controversial. There are some who argue that this prevents the medication from running out of the ear canal. Others believe that the cotton will absorb the medication and keep it from reaching the epithelium where it is needed. Still others state that the best method is to saturate a cotton wick with solution so that it will hold enough medication to be continually in contact with the inner ear tissue.

The physician may have recommended that the individual purchase an ear syringe to rinse out the ear canal. The pharmacist should counsel the patient on correct irrigating to achieve maximal benefit without causing damage to the ear canal. The correct method for rinsing the ears will be explained in the next lesson.

If directed by a physician, persons with recurrent swimmer's ear can use one of the commercially available OTC products or extemporaneously prepared preparations for prophylaxis. Patients should be advised that remedies containing acetic acid or alcohol will cause transitory painful stinging upon instillation.

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Give the Answers!

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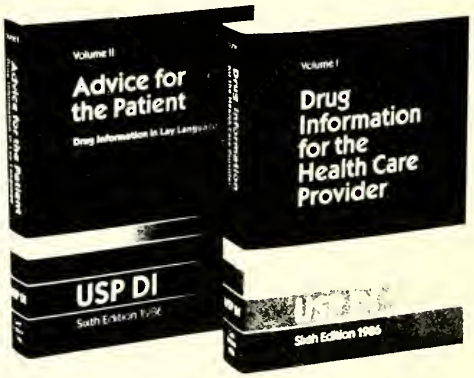

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Swimmer's Ear

continued from page 23

No foreign objects (e.g., matches, pencils, hairpins, paper clips or fingernails) should be inserted into the ear canal. Contrary to popular belief, it is unwise to vigorously wipe out the ears with cotton-tipped applicators. This procedure may push earwax and debris further into the ear canal, cause impaction of cerumen, or cause additional damage to the delicate lining of the ear.

Individuals who are susceptible to swimmer's ear and spend considerable time in swimming pools should follow their physicians' advice to prevent swimmer's ear from occurring. Chlorination of pools helps prevent growth of many microorganisms. However, chlorination procedures alone will not protect against swimmer's ear.

Persons being treated for swimmer's ear should avoid swimming or getting water in their ears during therapy. It normally takes 7 to 14 days for the condition to abate. If avoidance of water is not possible during this period, form-fitting ear stopples should be used.

Please turn to
Correspondence Course Quiz on Page 29.

FIGURE 2 Procedure for correct administration of ear drops.

Tilt the head to one side and turn the affected ear upward. Grasp the ear lobe and pull it upward and back to straighten the ear canal. For a child, pull the ear lobe downward and back. Fill the dropper and place the drops in the ear, but be careful to avoid touching the ear canal. Keep the ear tilted upward for 5–10 seconds, then gently insert a small piece of cotton into the ear to be sure the drops do not escape. Do not wash or wipe the dropper after use; replace it in the bottle and tightly close the bottle to keep out all moisture.

NORTH CAROLINA BOARD OF PHARMACY CENSUS OF LICENSED PHARMACISTS AND PHARMACIES

PHARMACISTS

Total number of pharmacists licensed and on roster April 14, 1986	5,145
Total number of pharmacists residing in North Carolina	4,244
*Inactive	316
Known status	3,928
Breakdown of employment in state:	
In retail community pharmacy (independent)	1,336
In retail community pharmacy (chain stores)	1,450
In hospital pharmacies	772
In nursing homes	8
In teaching and government positions	32
In manufacturing and wholesale	38
In sales and research	67
Other	115
Place of practice unknown	110
Under the age of 30	913
In the age group of 30–39	1,384
In the age group of 40–49	749
In the age group of 50–59	558
In the age group of 60–65	225
Over the age of 65	99
*Breakdown of inactive status:	
Retired	105
Unemployed or unknown	211
In-state female pharmacists	1,296
In-state male pharmacists	2,948
Total number of pharmacists who reside out-of-state	901
Out-of-state female pharmacists	343
Out-of-state male pharmacists	558

PHARMACIES

Total number of pharmacy permits on roster April 14, 1986	1,861
Number classified as retail pharmacies (independent)	839
Number classified as retail pharmacies (chain — 4 or more)	719
Number classified as hospital pharmacies	169
Number classified as nursing homes	17
Number classified as others	117

May, 1986

LOCAL NEWS

CHARLOTTE WOMAN'S PHARMACEUTICAL AUXILIARY
Charlotte, North Carolina

The Charlotte Woman's Pharmaceutical Auxiliary held its May meeting, Tuesday, May 13th at the Y.W.C.A. Mrs. Jesse Oxendine, president, presided. Mrs. Leslie Barnhardt gave the devotional.

Mrs. Barnhardt presented the following Board recommendations to the Auxiliary members:

1. That we increase the amount of our scholarship to $1,000.00 yearly.
2. That we give a gift of $200.00 to a Vietnamese pharmacy student who is in need of funds.
3. That we send Mission Air $200.00 to be used in their work.

All recommendations were adopted.

The Auxiliary honored Mrs. Gibbs Henley and Mrs. W. B. Hawfield by awarding them Honorary Life Memberships. Plaques were presented by Mrs. Tobie Steele.

Mrs. Douglas Corwin then presented Mrs. Johnie Bennick the Club's "Special Service Award." Mrs. Leslie Davis presented Mrs. Oxendine a silver wine cooler in appreciation for her service as president. Mrs. Oxendine is the state president and Mrs. Don Smith is state corresponding secretary for 1986–87.

Mrs. Douglas Corwin, using flowers as her theme, installed the following officers:

President — Mary Lou (Mrs. Leslie) Davis
First Vice-President — Marguerite (Mrs. Johnie) Bennick
Second Vice-President — Nancy (Mrs. W.B.) Hawfield
Recording Secretary — Virginia (Mrs. Tobie) Steele
Treasurer — Evelyn (Mrs. Gibbs) Henley
Historian — Laura (Mrs. C.D.) Cannon
Parliamentarian — Marguerite (Mrs. Gilbert) Colina
Advisor — Jewell (Mrs. Jesse) Oxendine

Virginia Steele
Corresponding Secretary

THE 1986 B.W. CO.® PHARMACY EDUCATION PROGRAM

Burroughs Wellcome Co. is pleased to announce the continuation of the Burroughs Wellcome Co. *Pharmacy Education Program* through 1986. This year, we will distribute $156,000 toward the program, bringing the total amount of awards over the past thirteen years to nearly $1,500,000.

The objective of the Burroughs Wellcome Co. *Pharmacy Education Program* is to bring all segments of pharmacy (retail—chain and independent, hospital, academic, and industry) together for the basic support of the future of pharmacy; i.e., to aid deserving students in completing their education.

Each year, pharmacists from every state, plus the District of Columbia and Puerto Rico, are invited to participate in the Burroughs Wellcome Co. *Pharmacy Education Program.* Pharmacists who participate have the opportunity to compete for educational grants which are presented to pharmacy schools and the educational foundations of six national pharmacy associations of their choice. Upon receipt, the pharmacy school involved establishes a Burroughs Wellcome Co. scholarship which will be awarded to an outstanding student to aid in the completion of his/her education.

When the program started in 1974, 52 students received grants of $250. In subsequent years, the program has gradually expanded to its present format of 156 winning pharmacists given the opportunity to donate: (1) $500 to the pharmacy school of his/her choice for the establishment of a Burroughs Wellcome Co. scholarship to be presented to an outstanding student; and (2) an *additional* $500 grant, issued in his/her name, and presented to the educational foundation of one of the following national pharmacy associations: American College of Apothecaries (ACA), American Pharmaceutical Association (APhA), American Society of

continued on page 31

Photo by Colorcraft

Inductees into the Fifty Year Plus Club of the NCPhA. Left to right: Roy W. Collette and Mrs. Collette, Nancy Pike Mitchener and Mr. Mitchener, H.C. Reaves, Sr. and his daughter Mrs. Susan Cooper, John D. Mitchell and Mrs. Mitchell.

Photo by Colorcraft

Charles Blanton, left, presents the Don Blanton Award for service to Pharmacy over the past year to Jean Paul Gagnon at the Annual Convention in Greensboro.

CORRESPONDENCE COURSE QUIZ

Swimmer's Ear

1. Cerumen exerts all of the following activities EXCEPT:
   a. lubricating the tissue lining the ear canal.
   b. stabilizing the eardrum to help hold its shape.
   c. assisting the normal health and integrity of the ear canal.
   d. aiding in the removal of micro-organisms.

2. Which of the following is the most applicable term in regards to swimmer's ear?
   a. An acute edematous condition
   b. A chronic edematous condition
   c. An acute serous condition
   d. A chronic serous condition

3. All of the following commercially available products contain 2.75% boric acid in isopropyl alcohol EXCEPT:
   a. Aurocaine.
   b. Swim-Ear.
   c. Aqua-Otic-B.
   d. Dri Ear.

4. The FDA advisory panel for OTC otic preparations has ruled that these products are safe and effective for self-use in which of the following conditions?
   a. Prevention of swimmer's ear
   b. Treatment of swimmer's ear
   c. Prevention and treatment of swimmer's ear
   d. Neither prevention nor treatment of swimmer's ear

5. When an antifungal agent is applied to the ear canal, it is most likely being used to treat an infection caused by:
   a. Candida.
   b. Herpes.
   c. Klebsiella.
   d. Streptococci.

6. Which of the following statements about the epithelial lining of the ear canal is true?
   a. It is thicker than most other epithelial linings in the body.
   b. It is a loose-fitting, flexible, easily manipulated tissue.
   c. It secretes the waxy substance that forms cerumen.

7. Inflammation of the auricle is best described as being otitis:
   a. auditoria.
   b. externa.
   c. media.
   d. tympana.

8. The term that best describes the pus-laden discharge from an infected ear canal is:
   a. ceruminogenic.
   b. keratoplastic.
   c. pyrogenic.
   d. seropurulent.

9. Consumers purchasing commercially available products for use with swimmer's ear should be advised of which of the following points of information?
   a. Swimming in pools with chlorinated water will prevent any future occurrence of swimmer's ear.
   b. These products can cause a burning or stinging sensation when applied.
   c. After applying the product, vigorously clean out the ear canal with a cotton-tipped applicator.

10. Which of the following is LEAST associated with the development of swimmer's ear?
    a. The amount and consistency of cerumen
    b. High temperatures
    c. Relative humidity levels
    d. The condition invariably occurs in both ears

11. The most commonly encountered causative microorganism in infection-complicated swimmer's ear is:
    a. *Clostridium difficile.*
    b. *Herpes simplex.*
    c. *Pseudomonas aeruginosa.*
    d. *Staphylococcus aureus.*

12. All of the following are correct statements about the auditory canal EXCEPT:
    a. it points slightly downward as it approaches the eardrum.
    b. it ends in a cul-de-sac at the tympanic membrane.
    c. it is slightly twisted.
    d. it readily repels foreign substances that enter it.

continued on page 30

Swimmer's Ear Quiz

continued from page 29

13. All of the following are appropriate vehicles for extemporaneous preparation of acetic acid solutions for use in the ear EXCEPT:
    a. anhydrous glycerin
    b. ethylene glycol
    c. isopropyl alcohol
    d. ethyl alcohol
14. Which of the following is most likely to retard the development of swimmer's ear?
    a. Abundant hair growing in the ear canal
    b. Narrow ear canals
    c. Excessive production of cerumen
    d. An acidic epithelial surface pH
15. The development of swimmer's ear is enhanced when the cerumen is:
    a. hard and contracted.
    b. soft and swollen.

ARE YOU?

Are you an active member, the kind that would be missed
Or are you just contented that your name is on the list?
Do you attend the meeting and mingle with the flock
Or do you stay at home and criticize and knock?
Do you take an active part to help the work along
Or are you satisfied to just belong?
Do you work with your committee and get right in and mix
Or leave the work to just a few and talk about the cliques?
Think this over member — you know right from wrong;
Are you an active member, or do you just belong.

Anon.

Cut Out or Reproduce and Mail

CONTINUING PHARMACEUTICAL EDUCATION
Swimmer's Ear

- Attach Mailing label from **The Carolina Journal of Pharmacy** in space provided (or print name and address) and mail completed questionnaire to: NCPhA, P.O. Box 151, Chapel Hill, NC 27514.
- You may submit completed questionnaires on a monthly, quarterly, or less frequent basis depending on which procedure is most advantageous for you in your pharmacy practice.
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2. a b c d	*5. a b c d*	*8. a b c d*	*11. a b c d*	*14. a b c d*
3. a b c d	*6. a b c d*	*9. a b c d*	*12. a b c d*	*15. a b c d*

Evaluation ☐ Excellent ☐ Good ☐ Fair ☐ Poor

How long did it take you to read the article and complete the exam? _____

RITE OF THE ROSES
Greensboro, N.C., April 21, 1986

Conducted by NCPhA Third Vice President William T. Sawyer

At the beginning of each NCPhA convention, we pause for a moment to note the passing of members of our organization during the previous year. Traditionally, this ritual involves the recitation of the names of those who have died since we last met, and the individual conducting the Rite will frequently recite some appropriate text or poem. Instead of this, I would prefer to use this occasion to reflect on its meaning.

Who is this ritual for? In all honesty, it is not really for those whose passing we acknowledge. Rather, it is for *us.* The ceremony encourages us to pause, to think of *our* loss — of family, of friends, of colleagues. It allows us to reflect on the impact that they and others have on our lives in so many known and unknown ways, and — of equal importance — to realize how much influence our own life may have on others. We do not have the opportunity that George Bailey, the protagonist in Frank Capra's very moving film, "It's a Wonderful Life" had, to see what the life of his family and his community would have been had he never been born. Nonetheless, we should use this occasion to develop a fuller appreciation of how our actions, in our personal lives and in our practice, may affect and influence those around us. And, hopefully, in doing so renew our commitment to a high standard of conduct. At this time, I will read the list of names of members of NCPhA who have passed away during the past year:

Bayless Cade Brooks, O'Brien, Florida
Milton Stanley Burt, Durham, N.C.
Constance M. Gordon, Weaverville, N.C.
Samuel Jenkins, Walstonsburg, N.C.
Melvin G. Kendrick, Greensboro, N.C.
Thomas R. Robinson, Jr., Goldsboro, N.C.
Matthew C. Savage, Roanoke Rapids, N.C.
Herman O. Thompson, Chapel Hill, N.C.
Delmar L. (Dale) Tysinger, Robbins, N.C.

WEDDING

Kathryn Ann Maxwell and KEVIN LEE ALMOND, both of Sanford were married Saturday, May 10, 1986 at First Baptist Church.

The bride, a graduate of Peace College and N.C. State University is a computer programmer/analyst at Research Triangle Institute in the Research Triangle Park. The bridegroom, a graduate of the UNC School of Pharmacy at Chapel Hill, is a pharmacist and owner of Sanford Pharmacy in Sanford.

The couple live in Sanford.

DEATHS

W. THOMAS ("TOM") BOONE, SR., Ahoskie, died Friday, May 2, 1986, after a lengthy illness. He was 65 years old. Boone owned and operated Boone Professional Pharmacy in Ahoskie until January 1, 1984. A past president of the North Carolina Pharmaceutical Association, he was selected 1982 Pharmacist of the Year and recognized at a dinner in Ahoskie. Boone was a World War II veteran, a graduate of the UNC School of Pharmacy, a director of the NC Pharmacy Foundation, a member of the American Pharmaceutical Association and the American College of Apothecaries. He was a past president of the Northeastern Carolina Pharmaceutical Association.

Pharmacy Education Programs

continued from page 27

Hospital Pharmacists (ASHP), National Association of Chain Drug Stores (NACDS), National Association of Retail Druggists (NARD), or the American Society of Consultant Pharmacists (ASCP). Again, the choice of national pharmacy association is up to the winners.

Pharmacists become eligible for the drawing (tentatively scheduled for August 21, 1986) by filling out and mailing an entry form to B.W. Co.® by the August 1 deadline. To be valid, the entry form must include both the pharmacy school and the national pharmacy association of their choice. Each of the 156 pharmacists will receive a suitably inscribed plaque in recognition of their being a winner. And *everyone who enters will receive a free gift—a replica of a 17th century pill tile.*

In 1985, over 45,000 entries were received, truly a testimonial to the interest within the pharmacy profession for the Burroughs Wellcome Co. *Pharmacy Education Program.*

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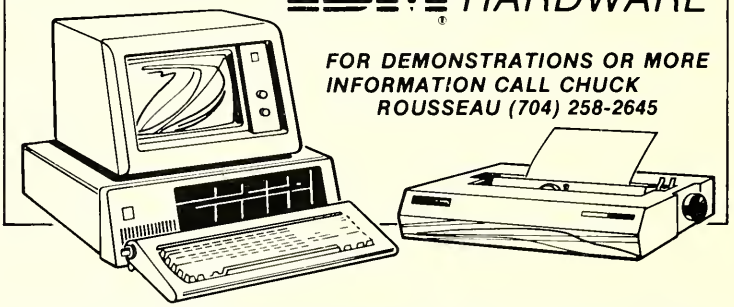

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Peggy Yarborough receives the A.H Robins Bowl of Hygeia Award from Michael E. Winters, Carolina Division Manager, A.H. Robins

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REPORT OF THE UNC AT CHAPEL HILL SCHOOL OF PHARMACY

106th ANNUAL CONVENTION OF THE NORTH CAROLINA PHARMACEUTICAL ASSOCIATION

APRIL 20-22, 1986 HOLIDAY INN FOUR SEASONS GREENSBORO

APRIL 21, 1986

I am particularly pleased to present the report of the School at the same site here in Greensboro where Midori and I were so warmly welcomed ten conventions ago.

Having just attended the American Pharmaceutical Association meeting in San Francisco last month and having the opportunity to exchange notes with my colleagues throughout the country makes me appreciate even more what we have in North Carolina. There is no question that we have a quality faculty, a quality student body and a quality environment. The environment includes North Carolina's "second-to-none" state-wide Area Health Education Centers and their pharmacy faculty and the many practitioner-instructors who assist us in our tasks. On behalf of the School and personally, I wish to express appreciation for all that you do for the School and for pharmacy. Appreciation is also expressed to those of you who continue to serve on the School's various committees and assist us in many other endevors.

The faculty continues to receive national recognition. To list just a few examples, Jean Paul Gagnon is serving as President, American Association of Colleges of Pharmacy and received the research award from the Academy of Pharmaceutical Sciences for his contributions to the Economic, Social and Administrative Sciences at the American Pharmaceutical Association meeting in San Francisco; Tim Ives is serving as Chairman of the American Society of Hospital Pharmacists' Ambulatory Care Special Interest Group; Kathy D'Achille was installed as Chairman-elect of the Clinical Pharmacy Section of the Academy of Pharmacy Practice, APhA; and Richard Kowalsky as the Chariman of the Nuclear Pharmacy Section. These and numerous other national activities have brought much focus to North Carolina. This, in turn, brings additional responsibilities and the obligation for us to lead.

To meet the challenges of dynamic and evolving School programs, organizational modifications were made this year. The Pharmacy AHEC faculty was integrated formally into the Division of Pharmacy Practice, and the Director of the Pharmacy AHEC now holds the position of Vice Chairman of the Division of Pharmacy Practice. The position is held by Steve Caiola. A Director of Continuing Education, a split position previously held by the Pharmacy AHEC Director, was created, and Dr. Betty Dennis was appointed. A. Wayne Pittman was appointed Director of a newly established Academic Development Office. These newly established offices will position the School to begin to meet the challenges of tomorrow today and to lead the nation in matters pertaining to the profession of pharmacy.

Continued on page 7

Dean Tom S. Miya

No one has documented the mountains in wintertime more beautifully than watercolorist Joe Miller. His work has shown in art galleries far and wide, attracting comment for their witty titles while establishing Miller's impressive reputation in the field.

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Table I.
Summary of Fall, 1984 and Fall, 1985 Enrollments in the B.S. in Pharmacy Degree Program

	Fall, 1984			Fall, 1985		
	M	F	Total	M	F	Total
Third Year	54	100	154	60	112	172
Fourth Year	56	93	149	52	95	147
Fifth Year	62	104	166	56	105	161
Total Undergrad.	172	297	469	168	312	480
Grad. Enrollment						72
Pharm.D. Enrollment						15
Fellows, Postdoctoral and Residents						17
Total Enrollment						584

The faculty, in addition to performing one of the best instructional tasks in the country published during 1984–85 74 research papers, 21 general articles, 1 textbook, 10 book chapters, 16 abstracts, 3 book reviews and numerous ancillary articles. Continuing education during 1984–85, delivered jointly with the AHEC's, offered 317 hours of instruction at 24 separate sites. For the current operational year this has been much expanded. The faculty during FY 1984–85 generated over $1,500,000 from competitive federal grants, foundations and private sources. The work of our current group of 72 graduate students, fellows and postdoctoral students is largely supported by these funds.

Student enrollment has remained relatively static. Table I shows comparisons between the fall of 1984 and 1985. I am pleased to report that for a variety of reasons, including your support and the School's recruiting efforts headed by Associate Dean Cocolas, the applicant pool shows signs of marked improvement in both quality and quantity. Note that the first-year pharmacy class (third year) is composed of 65% women. It should be noted that the UNC-Chapel Hill freshman class for 1985 is 61% women. Table II shows degrees conferred. With the total number of graduate students at 72, an all-time high, I would anticipate graduate degrees conferred to also rise dramatically during the next two years. We continue to be proud of our students. Virginia P. Suiter of Ahoskie was one of six students recognized nationally at the APhA Convention for scholarship, character and extracurricular activities. This is the sixth continuous year of national recognition of one or more of our students.

The School has graduated, on the average, 155 students with a B.S. Degree since the beginning of the 2–3 program. This year 146 students received the B.S. Degree. In addition, 6 students graduated from the Pharm.D. program. Twelve graduate degrees were completed. The data are summarized in Table II.

Significant this academic year was the selection of the School's first Hollingsworth Scholar, made possible by a bequest from the late

Continued on page 8

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Table II.
Degrees Conferred, Academic Year 1984–85

B.S. in Pharmacy		Doctor of Pharmacy		Graduate Degrees	
August, 1984	1	August, 1984	1	M.S.	11
December, 1984	27	May, 1985	5	Ph.D.	1
May, 1985	118				
Total	146		6		12

Mary L. Hollingsworth in the name of Joe Hollingsworth, a past president of this Association. The recipient was Patricia Leigh Parker of West Jefferson, North Carolina who will receive a stipend of $5,000.00 each year until the completion of her degree. We anticipate making an equivalent award each year to an incoming student.

Our Doctor of Pharmacy program remains small and of the highest quality and now recognized with the best programs. Because of the demand, we expect to expand the incoming class to 15 students in the fall of 1986.

There are many things left unsaid, and I apologize to those who are intimately involved in unreported activities. The School continues to make progress on many fronts.

A. Wayne Pittman, our Director of Academic Program Development, has written an interesting 20-year perspective on curricular development at UNC at Chapel Hill. It is included here for your edification. You will note that marked changes have occurred through the years as a result of national accreditation and University standards.

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PHARMACY FOUNDATION OF NORTH CAROLINA

The Pharmacy Foundation of North Carolina completed its 39th year of service to the School and to North Carolina during FY 1984–85. The School's great progress would not have been possible without the assistance of the Foundation. It has met a variety of unmet needs and has placed the UNC School in a highly competitive national stature.

During the 39th Annual Meeting the Board of Directors were joined by the School's Administrative Board during the morning session through lunch. Notable among the presentations were the continuing education needs assessment by Kathy D'Achille and Barbara Kramer's presentation of the School's Strategic Planning process which she is directing.

The luncheon session was highlighted by the presentation of a portrait of Howard and Mescal Ferguson of Randleman to the School by President Rogers. The portrait is an acknowledgement of the continuing support of the Foundation/School by the Fergusons. Howard is a 1924 graduate of the School of Pharmacy.

The total giving comparisons for 1982–83, 1983–84 and 1984–85 are $63,975, $174,977, and $336,311 respectively. These figures appear to represent a robust growth in giving. However, they reflect large gifts and bequests not normally anticipated. Gifts from solicitations for the same years amounted to $34,075, $31,352 and $42,923 respectively. The Foundation expresses gratitude to those of you who responded to the solicitation campaign. State appropriations do not meet the School's needs, and increasing dependence on extramural funds is anticipated.

I am pleased to acknowledge the initiative and hard work of Director Frank Yarborough who together with Peggy organized a picnic/continuing education at WRAL picnic grounds in Raleigh. It was supported by Glaxo Inc., and all proceeds were donated to the Foundation. The CE was presented by Fred Eckel, and all CE administrative costs were absorbed by the School.

Six Directors-elect were recognized at the Annual Meeting: Charles Blanton, Sara Hackney, Whit Moose, and Artemus West (elected by the NCPhA membership); William Edmondson and Pamela Joyner (elected by the Board of Directors). By action taken by the Board of Directors, the category of Director-elect was abolished. Beginning with FY 1986–87 the newly-elected Directors will be installed and seated on the Board during the year of their election and serve a four-year term. Six members of the twenty-four member Board of Directors will rotate each year. There will be no election in 1986–87.

A special request by Director Tom Burgiss was made in behalf of the School for underwriting an "Impaired Pharmacist" awareness program. The request was approved for $15,000. It is anticipated that the School will reimburse the Foundation at a later date.

I am particularly pleased to report that by a prudent investment policy and judicious spending the total assets of the Foundation at the end of December 1985 reached approximately $1.67 million. This is a remarkable growth considering that ten years ago the total assets were less than $400,000. The growth of the funds is a result primarily from *three* items: (1) large bequests and gifts, (2) judicious use of funds which allowed available currently expendable funds to be invested, and, not the least (3) the exemplary performance of our portfolio manager.

The School will require continued assistance from the Foundation. I thank all of you for your support and request your continuing loyalty.

Should any of you desire more information regarding the Foundation, please contact me, President Ralph Rogers, or any member of the Board of Directors. The list of the Board of Directors is attached.

Respectfully submitted,
Tom S. Miya, Ph.D.
Dean, School of Pharmacy
Secretary, Pharmacy Foundation

PA ADDS TO REWARD; ASKS CYANIDE STUDY

The Proprietary Association (PA), representing U.S. makers of nonprescription medicines sold over the counter (OTC), announced an additional reward of up to $300,000 for arrest and conviction of the person or persons responsible for the recently announced Excedrin® Extra-Strength capsule poisonings in the Seattle, Washington, area.

This brings to $1 million the rewards offered by the PA for drug tampering cases dating back to the 1982 deaths in the Chicago area.

The PA also called for government review of the easy public availability of cyanide, a deadly poison.

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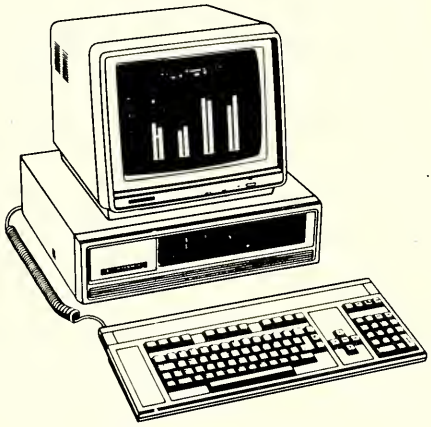

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REPORT ON THE STUDENT BRANCHES OF NCPhA

by William Whitaker Moose, Jr.
President 1985–1986
Student Branches of APhA-NCPhA

106th Annual Convention North Carolina Pharmaceutical Association April 20-22, 1986 Holiday Inn, Four Seasons Greensboro

The membership this year was approximately 80% of the Pharmacy School Student Body. At the beginning of the year the Student Branch had a pig pickin' for the students with a very large turnout. The leftovers from the bar-b-que were donated to the Carrboro Community Kitchen.

At our meetings this year, we had speakers from many different aspects of pharmacy — community, clinical, etc.

This year was a year of change at the University and we were proud to be a part of this change. We had several new projects this year as well as our old standards — hypertension and diabetes screening clinics. The new osteoporosis clinic was held at our local mall and shopping centers.

Our big project this year was the Patient Counselling Competition. The purpose of this contest was to increase student awareness of the need for patient counselling. Over $2,000 was donated from Burroughs Wellcome, UpJohn, Pharmacy Foundation and the Pharmacy Alumni Association.

At our Awards Ceremony held at the Institute of Pharmacy, Dean Cocolas awarded Tommy Jones of Cary, N. C. $250 and a trip to San Francisco, CA to compete in the national competition at the APhA Convention.

Also at the convention in San Francisco, Virginia Suiter of Ahoskie was awarded the $500 Chloraseptic Leadership Award.

Another member, Libby McGlohan of Durham, was elected Alternate Regional Delegate for our region in Atlanta, GA.

Another change we made this year was replacing Dr. Robert Shrewsbery after his many years of fine service as faculty advisor. Dr. Dennis Williams of the Pharmacy Practice Division is our new advisor.

We also changed our terms of office from August to August to January to January. We have also added a President Elect position. We feel that this will make the transition between offices much smoother and will make the organization run more easily.

We would like to thank Al Mebane and everyone at the Institute of Pharmacy for their help this year. We could not have done it without them.

I would also like to thank my wife, Selwyn, for her help and support throughout the year.

Don Peterson

Ralph P. Rogers, Executive Vice President of North Carolina Mutual Wholesale Drug Company, Durham, has announced the promotion of Donald V. Peterson to general manager. Peterson, a 1972 graduate of the School of Pharmacy, University of North Carolina, has been employed at Mutual Drug for 17 years. He has served on numerous committees of the North Carolina Pharmaceutical Association.

Other promotions announced were: L. Milton Whaley to sales manager and treasurer, W. E. Rogers to controller, and D. E. Tilley to purchasing director.

DICKINSON'S PHARMACY

by Jim Dickinson

The hesitant profession? Pharmacists have seen what's happened to physician malpractice/liability premiums, and in many cases, also what's happened to their own.

They've heard the disparagers of generics exploit any and all chinks of theoretical uncertainty about bioequivalence.

And they've heard the profession's futurists strum beguiling tunes about "new roles" in the world of tomorrow that's just around the corner.

Yet pharmacists, for the most part, keep on being just pharmacists. When they're given new roles, many just don't take them. In Florida, where they've had a limited license to prescribe for four months or more, observers report little evidence of pharmacists prescribing within that new law.

Loss of liability insurance coverage, coinciding with the new law, surely had something to do with that — but where is the spirit of adventure that anything new requires? Did Dan'l Boone go out on the new frontier only after his insurance policy had been renewed?

"Ours must not be a hesitant profession," USP executive associate Joseph G. Valentino, a pharmacist-attorney, cajoled graduating pharmacists at Rutgers in June. Pharmacists must seek a decision-making role, he said.

That may not be possible much longer, Joe. That role may have found pharmacy already.

In a recent Pennsylvania Superior Court decision, pharmacists — along with other health professionals — were found to have an enforceable legal duty to second-guess prescribers. That's never happened in a court of law before.

In the case, *Riff v. Morgan Pharmacy*, concerning unwise prescribing of Cafergot, the court declared:

"Fallibility is a condition of the human existence. Doctors, like other mortals, will from time to time err through ignorance or inadvertance. An error in the practice of medicine can be fatal; and so it is reasonable that the medical community including physicians, pharmacists, anesthesiologists, nurses and support staff have established professional standards which require vigilance not only with respect to primary functions, but also regarding the acts and omissions of the other professionals and support personnel in the health care team. Each has an affirmative duty to be, to a limited extent, his brother's keeper."

Verdict: Pharmacist guilty.

Sentence: Servitude in market activism; it's too late to continue trying to be the "hesitant profession."

Drug utilization review responsibilities under PPO/pharmacy services administrative organizations (PSAO) contracts are one way of finding a new role, making decisions, and being your brother's keeper. In its new national PSAO, RxNet, the National Association of Retail Druggists has adopted the responsible requirement of DUR as a condition of participation.

PSAOs, now either under way or in the planning stages in all but three states (and even they are wistfully eyeing the concept) represent the most dynamic survival-success mechanism to happen in pharmacy since World War II, when the large corporations began taking over.

In Kansas City in May, top health buyers for General Motors and the Mutual Insurance Company of New York told NARD's first annual PSAO conference that prescription program administrators would actually *prefer* to give their beneficiaries the independent pharmacy option. There was even a hint that they would pay more per Rx if longer-term, overall cost efficiencies could be demonstrated.

In an effective PSAO, with its combination of individual entrepreneurship and group discipline, independent pharmacy has a way of marketing itself against the mail order operations and the chains, without violating the antitrust laws that have for so long prevented them from fighting fire with fire in a fair, competitive marketplace.

Hesitant?

This feature is presented on a grant from Mylan Pharmaceuticals, in the interests of promoting the open discussion of professional issues in pharmacy. Mylan Pharmaceuticals accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of Mylan Pharmaceuticals.

MILTON W. SKOLAUT AND RHETA L. SKOLAUT NAMED HONORARY MEMBERS OF ASHP

Pharmacists Milton W. Skolaut and Rheta Leverett Skolaut were granted honorary memberships in the American Society of Hospital Pharmacists during opening ceremonies at the 43rd Annual ASHP Meeting in Denver, Colorado, on June 2, 1986. In addition, a certificate of commendation was awarded to Mr. Skolaut during the first meeting of the ASHP House of Delegates later that day. The Skolauts are long-time members of ASHP; Mr. Skolaut is a past president of the Society and served as Treasurer for 15 years, from 1968 until 1983. He currently holds the position of Treasurer Emeritus.

Milton Skolaut was born in San Antonio, Texas. He received a B.S. degree from the College of Pharmacy, University of Texas, Austin, in 1941, and did an internship in pharmacy the following year at The Johns Hopkins Hospital, Baltimore. Mr. Skolaut began his career in Baltimore, working in the pharmacy departments at University Hospital and The Johns Hopkins Hospital. During this time he was also an instructor in the School of Pharmacy at the University of Maryland, Baltimore. Between 1952 and 1969 he was Chief, Pharmacy Department and Central Supply, at the Clinical Center of the National Institutes of Health in Bethesda, Maryland. Among his accomplishments at NIH were the establishment of a pharmacy-operated central supply, a radiopharmacy service, and one of the first centralized i.v. admixture services.

Skolaut joined the staff at Duke Hospital in January 1970 and was named director of the Department of Pharmacy later that year; he also holds a faculty appointment as adjunct assistant professor, University of North Carolina School of Pharmacy, Chapel Hill. Among his major accomplishments at Duke were the establishment of a new sterile processing department and an operating suite pharmacy department in the new Duke Hospital North. During Skolaut's tenure at Duke, the pharmacy added unit dose and i.v. admixture services, full total parenteral nutrition services, clinical services, and a residency training program.

In addition to his many contributions to ASHP, Mr. Skolaut has held various committee appointments in the North Carolina Society of Hospital Pharmacists and has participated in more than 30 symposiums and meetings in the United States and abroad. He has published several articles on the topics of pharmacy central supply and innovative pharmacy services. He received the Harvey A. K. Whitney Lecture Award, American hospital pharmacy's highest honor, in 1979.

Milton and Rheta Skolant

Rheta Skolaut, a native of Georgia, received a B.S. degree in pharmacy from the University of Georgia School of Pharmacy, Athens, in 1956, at which time the school named her "Woman Pharmacist of the Year." She held the position of chief pharmacist at Memorial Hospital, Waycross, Georgia; Athens General Hospital, Athens; and Memorial Hospital of Chatham County, Savannah. In the last position she was responsible for designing a unique drug distribution and centralized patient charging system in the pharmacy. Mrs. Skolaut also was a staff pharmacist at Watts Hospital in Durham, North Carolina.

Continued on page 14

Honorary Members Named

Continued from page 13

Mrs. Skolaut is a member of ASHP, the American Pharmaceutical Association, and the Southeastern Society of Hospital Pharmacists. She has served as vice president and secretary treasurer of the Southeastern Society and was named "Pharmacist of the Year" by that group in 1978. She has also served on the Board of Directors of the American Lung Association of North Carolina. The Skolauts are both members of the North Carolina Pharmaceutical Association and were selected in 1983 and North Carolina "Pharmacists-of-the-Year," the first couple to receive that honor.

Honorary membership in the American Society of Hospital Pharmacists requires the unanimous affirmative vote of the Board of Directors. Only twenty-two men and women currently hold honorary membership in ASHP.

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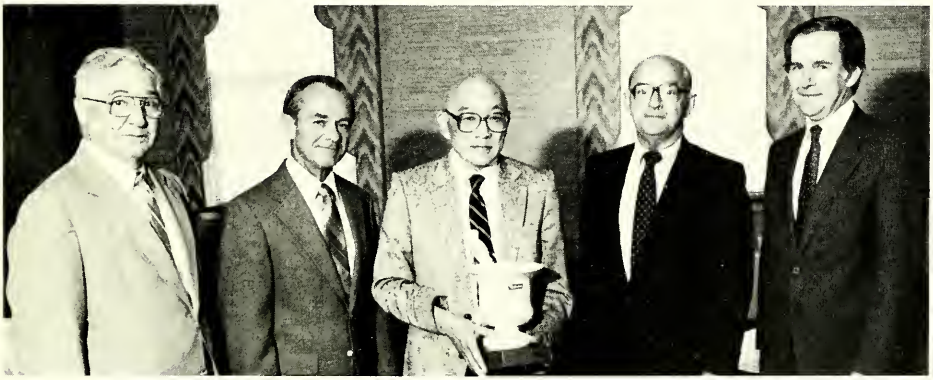

Upjohn's Pharmacy and Trade Relations Director, Jack M. Newcomb, presented a check for $15,000 to the UNC Pharmacy School Dean Tom Miya to assist in the development of a pharmaceutics laboratory. Director Newcomb also presented the School with a porcelain mortar and pestle commemorating the centennial of The Upjohn Company based in Kalamazoo, Michigan. Dr. James Swarbrick, Chairman of Pharmaceutics, and Claude Paoloni, Assistant to the Dean for Special Projects, were also present.

BEVERLY D. HELTON RECEIVES ROGERS AWARD

Beverly Diane Helton, Ellenboro, received the 8th Annual Ralph Peele Rogers Memorial Award for excellence in Pharmacy Administration. The award is presented by the family of the late Ralph P. Rogers, owner of Rogers Drug Company of Durham for fifty years.

The Rogers Award includes a dinner at the Carolina Inn for the recipient and her family, with representatives of the Division of Pharmacy Administration, and a check for five hundred dollars. Candidates are selected by the Pharm Ad faculty based on interest in community pharmacy and superior performance in class. Interviews narrow the list and the successful student is selected based on all of the mentioned criteria and a paper on pharmacy administration. Miss Helton's paper "Unique Opportunities in Pharmacy Today" is printed below. Previous recipients are Scott Dinkins, 1978; Jo M. Travis, 1979; Susan Speir, 1980; Kent Tapscott, 1982; Sherri Furr, 1983; Melanie Spencer, 1984; Stephen Ruddy, 1985.

UNIQUE OPPORTUNITIES IN PHARMACY TODAY

by Beverly D. Helton

Over the past decade, numerous opportunities for pharmacists in our society have emerged. Pharmacists have been shown to be among the highest respected professionals in the United States today; the public is increasingly turning to the pharmacist as THE source of drug information. Pharmacists are finally beginning to be recognized as more than a man in a white coat who counts pills, types labels, and receives a $30,000/year salary. Along with this recognition and increasing respect, however, comes the obligation the pharmacist has to find new, expanded methods of providing drug information to the public. Never before in the history of pharmacy has the individual pharmacist had the diversed opportunities for service as he does today!

The entrepreneurial pharmacist of today may elect to start an independent pharmacy; this one store, if successful, may lead to a "chain" of stores

Photo by Colorcraft

Ralph Rogers Jr. presents a check for five hundred dollars to Beverly Helton, as part of the Ralph Peele Rogers Memorial Award.

in the future. One does not simply "start" an independent pharmacy, however — business training, careful planning, a lot of hard work, and perhaps a little luck are all key elements to a successful business. An independent store can be successful, however, even in light of pricing competition, better recognition on a state-wide basis, etc. of chain stores. The people that pharmacies serve have seen to this! Many people desire the more personal, relaxed atmosphere that many independents offer: the type of atmosphere where a customer is greeted by name at the door by a clerk (or even the pharmacist!); the type of atmosphere where the customer feels free to discuss drug-related questions, other problems, or even the score of the latest ACC basketball game with the pharmacist. The pharmacist who offers himself as more than a person who *fills* the prescription has a much greater chance of success in the independent pharmacy setting.

The emergence of the clinical pharmacist over the past decade has opened up many opportunities for pharmacists. When one hears "clinical pharmacist", one usually envisions a pharmacist with an advanced degree working in a hospital setting. But opportunities for clinical service exist in the retail setting, too. A variation to the traditional independent pharmacy might be a pharmacy located within a Medical Park. The pharmacists would have access to patient medical records and be available for consultation with any of the MDs, dentists, etc. in the Park. The pharmacists would provide counseling to each patient receiving prescriptions. And, because this pharmacy would only stock prescription and OTC drugs, the pharmacy would have a more professional atmosphere. The pharmacist would have more time for interactions with his patients, and patients would be assured that answers to their questions would not be interrupted by other customers asking where the motor oil is. Pharmacy customers today are requesting, even demanding, more information on the drugs they are taking; therefore, this type of pharmacy would answer the demand for these counseling services. The success of such stores today can attest to the profitability of such a venture.

An additional opportunity for pharmacists lies in the area of specialty units. With today's advancements in medical technology, hospital patients are being returned to their homes more rapidly than a few years ago. There is a growing need for some health care services for these patients — services to provide IV admixture, hyperalimentary solutions, etc. The entrepreneurial pharmacist could feasibly start his own home health care company. Not only would the pharmacist be involved in mixing and preparing drugs for the patient but also in distribution of the drugs, assisting in follow-up of the patient, and in the clinical management of the service.

The opportunities available to the pharmacists of today are numerous — one only has to be willing and courageous enough to accept the challenges these opportunities present. No longer do graduates and practicing pharmacists have to accept jobs only in traditional retail, industry, or hospital settings. The pharmacists of today are limited only by the scope of their imagination.

Photo by Colorcraft

Rogers Award program participants: Jean Paul Gagnon, Beverly D. Helton, Ralph P. Rogers, Jr., Al Mebane.

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USP TIPS AGAINST TAMPERING

The deaths which have occurred from the deliberate introduction of dangerous substances into medicines have made us all aware that no matter how good a program of drug testing, regulation, and protective packaging may be devised, total security cannot be provided against all the possibilities that sick minds may invent to tamper with our medicines or other consumer goods.

In view of this, the following information is offered to help you detect possible tampering with over-the-counter (OTC) medicines.

Protecting Yourself

The first step in protecting yourself is an awareness that tampering, however unlikely, may occur. Then it's up to you to apply some common sense. Here are some general suggestions:

- When selecting a drug product, consider among other things, how it is packaged and the nature of the dosage form (tablet, capsule, liquid, etc.).
- Take a few seconds to visually inspect the outer packaging of the drug product before you buy it and again as you open it at home.
- If the medicine has a protective packaging feature, it should be intact.
- Never take medicines that show even the slightest evidence of tampering or don't seem quite right.
- Never take medicines in the dark or in poor lighting. Look at the label and the medicine *every time* you take a dose.

Tips for Checking Your Medicine

Packages

- Are there bits of paper or glue on the rim of the container indicating it once had a bottle seal?
- Does the cotton plug or filler in the bottle appear to have been removed and put back in?
- Does the outer covering appear to have been disturbed, unwrapped, or replaced?
- Is the bottle overfilled or underfilled?
- Does a plastic or other shrink band around the top of the bottle appear distorted or stretched, as though it had been rolled down and then put back into place? Is the seal missing? Has the band been slit and retaped?
- Is the cap on an unsealed container tight?
- Are the information and the lot number on the container the same as that on its outer wrapping or box?

Liquids

- Is it the usual color and thickness?
- Are there particles in the bottom of the bottle or floating in the solution?
- Is a normally clear liquid cloudy?
- Does it have a strange or different odor (for example bleach, acid, gasoline-like, or other pungent or sharp odor?)
- All eye drops are required to be sealed at the time of manufacture to protect their sterility. If there is any sign of a broken or removed seal on eye drop packaging, the product should not be used.

Tablets

- Has their appearance changed? Is the color different? Do they have unusual spots? If they normally are shiny and smooth, are some dull or rough?
- Do the tablets have a strange or different odor or taste?
- Are the tablets moist rather than dry?
- Are the tablets all the same size and thickness?
- If imprinted, do all tablets have the same imprint? Is the imprint missing from some?

Capsules

- Are they cracked or dented?
- Do they have their normal shiny appearance or are some dull or have fingerprints on them as though they have been handled?
- If imprinted, do they all have the same imprint? Is the imprint missing from some? Are the imprints properly aligned?
- Are they of uniform size and color?
- Do the capsule contents appear to be of equal amounts? Are the capsules all the same length?
- Do they have an unexpected or unusual odor?

Tubes and jars (ointments, creams, pastes, etc.)

- Check the bottom as well as the top of a tube, especially if it is a metal tube crimped up from the bottom like a toothpaste tube. It should be firmly sealed.
- Are ointments and creams smooth and non-gritty? Have they separated?

PHARMACISTS: You are encouraged to reproduce this information and provide it to your customers.

Whit Moose, President of the Student Branches, addressing the Annual Convention in Greensboro.
Photo by Colorcraft

EXAMPLES OF PACKAGING

Package	Description
Film wrappers	Film wrapped and sealed around the drug dosage form and/or its container
Blister/strip packs	Individually sealed dosage units
Bubble packs	Product and container sealed in plastic, usually mounted on/in a display card.
Shrink seals/bands	Bands or wrappers which fit tightly around cap and container
Foil, paper, or plastic pouches	Sealed individual packages
Bottle seals	Paper or foil sealed to bottle mouth under cap
Tape seals	Paper or foil sealed over carton flap(s) or bottle
Breakable caps	Plastic or metal caps, parts of which must be broken to remove

Keep in mind that not every change in the appearance or condition of a product means that the package has been tampered with. The manufacturer may have changed the color or the packaging of a medicine or the product may be experiencing deterioration or may have had rough or unusual handling in shipping. Also, some minor product variations may be normal.

Whenever you suspect anything to be out of the ordinary or unusual about a medicine or its packaging, have your pharmacist look at it. Pharmacists know what the usual appearance of the packaging and the product should be. If there are genuine problems with a drug product or medical device, your pharmacist may report it to the Drug Product Problem Reporting Program (DPPR), which is coordinated by USP and funded by the FDA, with the cooperation of the American Society of Hospital Pharmacists and state pharmacy associations. *USP — Copyright 1986*

CORRESPONDENCE COURSE

ADVISING CONSUMERS ON NASAL DECONGESTANTS

by Thomas A. Gossel, R.Ph., Ph.D.
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Ohio Northern University, Ada, OH
and
J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati, Cincinnati, OH

Goals

The goals of this lesson are to:

1. discuss the actions and uses of OTC nasal decongestants;
2. explain how to advise patients on their use.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. identify the pharmacological action of the described OTC nasal decongestants;
2. choose the appropriate agent for a given situation;
3. explain the proper technique for instilling the products;

Nasal congestion, more commonly referred to as stuffed-up or stuffy nose, is usually caused by the common cold. However, allergic rhinitis, bacterial infection, local or viral inflammation, anatomical defects and emotional upset can also result in nasal congestion.

Congestion occurs in the nose when capillaries serving the nasal mucosa respond to irritants (both external and internal) by dilating. Fluid seeps from these enlarged blood vessels into the tissues of the sinus areas and nasal cavity causing localized edema with swollen nasal passages. This is all part of the natural inflammatory response. Histamine, due to its vasodilatory effects is the causative agent making breathing through these inflamed passages difficult. Since fluid exudation increases (a normal cholinergic activity) with the common cold, sinus and nasal discharge can accompany the congestion.

In this lesson, the actions and uses of nasal decongestants will be highlighted with an emphasis on products that are safe and effective for OTC use. Several of these were formerly available only on prescription. Consumer advice will be presented, along with suggestions to aid individuals in overcoming the decongestant "habit."

Function Of The Nose

The nose alerts us to pleasant, unpleasant and noxious odors. It is the beginning of our "natural humidifier." In order for the lungs to function properly, air delivered to them from our environment should be at or near 100% relative humidity. Relative humidity refers to the amount of moisture in the air as compared to the total amount of water that the air can contain at that temperature. For example, when it is raining, the air is at 100% relative humidity. One rule of nature is that warm air holds more moisture than cold air.

Usually, the air around us ranges from 40 to 75% relative humidity. The numerous blood vessels in the nose raise the relative humidity of inspired air by warming it so that it can hold more water. They also supply moisture. This air is then carried past the nasopharynx and laryngeal area where it picks up even more moisture. These

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Nasal Decongestants

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same blood vessels, when dilated, cause nasal congestion.

The nasal mucosa contains cells which secrete mucus that is normally transported by ciliary action as a continuous layer backward into the nasopharynx, along the pharyngeal wall, and then into the esophagus where it is swallowed. This fluid also lubricates the pharyngeal and laryngeal mucosal surfaces in the process. When excessive fluid is produced, it can drain out of the nostrils (i.e., during the common cold or hay fever) or drain into the trachea irritating the tissues (i.e., post nasal drip).

Nasal Decongestants

Chemically, nasal decongestants are sympathomimetic amines. Pharmacologically, they stimulate the alpha adrenergic receptors of vascular smooth muscle which are excitatory, and constrict dilated arterioles. Dilated vessels located within the nasal mucosa become smaller and less engorged with blood. This decreases the edema and consequently improves nasal ventilation and drainage. Headache resulting from congested sinuses may also be alleviated.

Decongestants can be taken orally or applied directly to the nasal mucosa. Phenylpropanolamine and pseudoephedrine are effective orally. Neither shows significant activity when applied locally.

Effective topical decongestants are ephedrine, levodesoxyephedrine, naphazoline, oxymetazoline, phenylephrine, propylhexedrine and xylometazoline. Trade names for those products are listed in Table 1.

Ephedrine has bronchodilatory, CNS stimulant, and vasopressor (when given by injection) activity. It is one of the oldest drugs, and has been used in China for centuries. Ephedrine has been used as a nasal decongestant in this country since the mid-1920's, but its use has decreased in recent years and now is almost obsolete.

Naphazoline is reportedly a more potent vascoconstrictor than the other short-acting

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Alec Clelland and family who installed the new decor package in Bordeaux Pharmacy in Fayetteville. We are proud to have been a part of this project.

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TABLE 1
Representative OTC Nasal Decongestants

Topical Ingredients	OTC Products
Ephedrine	Efedron, Vatronol
Levodesoxyephedrine	Vicks Inhaler
Naphazoline	Privine
Oxymetazoline	Afrin, Dristan Long Lasting, Duramist Plus, Duration, Neo-Synephrine 12 Hour, Nostrilla, Sinex Long Lasting
Phenylephrine	Alconefrine, Allerest, Coricidin, doktors Nose Drops, Duration Mild, Neo-Synephrine, Nostril, Rhinall, Sinarest, Sinex
Propylhexedrine	Benzedrex Inhaler
Xylometazoline	Chlorohist-LA, 4-Way Long Acting, Neo-Synephrine II Long Acting, Otrivin, Sinutab Long Lasting
Systemic Ingredients	**OTC Products**
Phenylpropanolamine*	Decongestant-P, Propagest, Rhindecon
Pseudoephedrine*	Afrinol, Cenafed, Kodet SE, Novafed, Sudafed

*both of these agents are included in numerous combination cough and cold remedies

Ephedrine, levodesoxyephedrine, naphazoline, phenylephrine, and propylhexedrine are relatively short-acting topical nasal decongestants. The dosage regimen is usually every 3 to 4 hours.

topical decongestants. A 0.05% solution of naphazoline is equally effective as a 0.5% solution of ephedrine or phenylephrine.

Phenylephrine has been widely used in a variety of systemic cold remedies for many years. It is a safe and effective decongestant when used orally.

Levodesoxyephedrine and **propylhexedrine** are volatile amines that can be incorporated onto a cotton wick and used in an inhaler (e.g., Benzedrex, Vick's Inhaler). The characteristic smell is due to the volatile oils that are added, not the active ingredient. Since they are equally effective, the choice of which inhaler a person prefers is based on subjective opinion or personal preference.

Oxymetazoline and **xylometazoline** are longer acting than the aforementioned topical agents with some individuals obtaining 10 to 12 hours of decongestant activity from a single dose. They, most specifically oxymetazoline, have captured a major share of the OTC market place. Apparently their more convenient dosage regimen and lower incidence of rebound congestion (to be explained shortly) makes them agents of choice. These two agents were among the first of the OTC drug products shifted from prescription only to OTC status during the flurry of such activity in 1981 and 1982.

Phenylpropanolamine and **pseudoephedrine** are safe and effective oral agents for self-treatment of "stuffy" nose. After absorption and distribution to the vascular bed in the nasal mucosa, they provide a less intense but more sustained action than the short-acting topical agents.

Relatively speaking, phenylpropanolamine exerts a greater CNS stimulatory effect than pseudoephedrine. In fact, phenylpropanolamine has been determined to be safe and effective by the FDA advisory panel that reviewed OTC appetite appeasers. It is the principle active ingredient of most diet aid products.

Pseudoephedrine reportedly causes fewer CNS effects than does phenylpropanolamine, and is available in regular and sustained-action oral dosage forms.

Adverse Effects

Used as directed, nasal decongestants rarely cause adverse effects, especially the topically applied agents, because very little is absorbed into general circulation. There have been isolated reports that phenylpropanolamine, in very high doses, may cause severe headaches and hypertensive reactions. All of the decongestants, because they are sympathomimetic amines, have a potential for causing various CNS effects. These adverse reactions are listed in Table 2.

The systemic sympathomimetics have the potential to aggravate certain disease states including diabetes, hypertension, heart and thyroid disease. Since sympathomimetics are

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Nasal Decongestants

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adrenergics and have adrenalin-like action, they may modify insulin release as well as the breakdown of glycogen to glucose. In nondiabetics, this is of no consequence because they can readily readjust blood sugar levels. In some diabetics, however, sympathomimetics can affect blood sugar levels enough to cause serious problems.

Hypertensive patients have excessively constricted blood vessels. Adding a vasoconstrictive drug into the circulation can worsen the condition.

If a patient has cardiac arrhythmias due to overstimulation by the sympathetic nervous system, these adrenergic agents can exacerbate the problem. There is also an increased chance of anginal attacks in patients with that disease.

Patients with hyperthyroidism may also have problems with sympathomimetics. The additive action of high blood levels of thyroid hormones coupled with exogenous sympathomimetics can cause cardiac arrhythmias.

All of the above are "use with caution" situations, not strict contraindications. The products should be used with caution or under the supervision of a physician. Therefore, manufacturers of OTC products containing systemic sympathomimetics are required to place a warning on the label stating: "Except under the advice of a physician DO NOT take this product if you have high blood pressure, heart disease, diabetes or thyroid disease."

Consumers seeking alternative products for their stuffy nose should be directed to the topical decongestants. They are not appreciably absorbed and do not reach significant systemic blood levels. They, therefore, do not bear the above warning statement.

Another "adverse" effect caused by nasal decongestants is **rhinitis medicamentosa (rebound congestion).** The consumer may complain that the product currently used no longer affords adequate relief, or that the decongestant action doesn't persist as long as it formerly did. It has been reported that up to five percent of all visits to ear, nose, and throat specialists are for rebound congestion.

The exact mechanism for rebound congestion is not known, but a plausible explanation is that prolonged overcontstriction of the blood vessels in the nose induces local submucosal hypoxia (insufficient oxygen). That, in turn, causes hyperemia (excessive blood flow) into the hypoxic area and results in vasodilation. Another theory is that vasoconstrictors possess beta-adrenergic stimulant action along with their predominant alpha-adrenergic activity. The beta effect is not normally pronounced when the drugs are used correctly. When they are used too frequently or for prolonged periods of time, the beta stimulant action becomes more dominant and outlasts the alpha effect. This leads to secondary vasodilation and nasal vessel engorgement.

Rebound congestion can be expected whenever topical decongestants are used longer than 3 to 5 days. It is more prevalent with the short-acting topical agents, less so with the long-acting topicals, and rare with the systemic agents.

The simplest method for treating rebound congestion is to completely withdraw the topical vasoconstrictor. However, patient acceptance of this method is poor because it can result in bilateral vasodilation and total nasal obstruction. A more acceptable method is to discontinue the medication in one nostril at a time. The patient can continue to use the medication correctly in the other side of the nose until the rebound condition subsides in the drug-free nostril. This normally takes one to two weeks. Withdrawal from the other side of the nose can be undertaken when the first side is clear.

An alternative approach is to substitute a

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TABLE 2
Adverse Effects Reported For Systemic Decongestants*

Bradycardia
Cardiac arrhythmias
CNS stimulation
Coma
Deep sleep
Dizziness
Drowsiness
Headache
Insomnia
Nausea
Nervousness
Palpitations
Rebound hypotension
Sweating
Trachycardia
Transient hypertension

*Not all effects have been reported for all systemic nasal decongestants.

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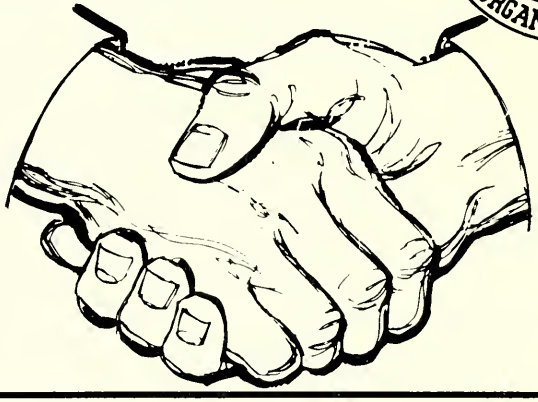

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Nasal Decongestants

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systemic decongestant for the topical agent. The patient can use saline drops or spray during the weaning period. A saline product has the dual function of keeping the nasal mucosa moist, while providing psychological assistance to those individuals who have become dependent on introducing medication into their nose.

Patient motivation and compliance is absolutely essential if the condition is to be relieved. The patient should understand why the condition exists. He should be told that a week or so of discomfort may follow discontinuance of the medication, but that this will gradually decline in severity until there is no further need for continued medication use.

Drug Interactions

The OTC label warning mentioned earlier continues to read: "Do not take this product if you are taking a prescription antihypertensive or antidepressant." This warning refers to a potential interaction between monoamine oxidase inhibitors (MAO) and sympathomimetics, which is considered an absolute contraindication. Since MAO inhibitors decrease the metabolism of sympathomimetics and the neurotransmitters that indirect-acting sympathomimetics release, they can potentiate the activity of the sympathomimetics. Hypertensive crisis has been attributed to this interaction.

Systemic sympathomimetics can also inhibit the action of guanethidine (Ismelin®) and guanadrel (Hylorel®). Concurrent use with either of these agents is not recommended.

Topical decongestants are neither contraindicated nor implicated in any drug interactions.

Topical vs. Systemic Decongestants

The question of which decongestant is best is based on subjective preference, not scientific fact. Systemically administered products are claimed to provide a more effective decongestant action because they reach all parts of the nasopharyngeal and sinus mucosa regardless of the extent of clogging of the nasal passages. The introduction of topically applied drugs may be impeded by severe congestion.

The effect from systemic drugs is slower in onset, but supposedly more prolonged since topically applied medication is washed away by the action of respiratory tract fluids. However, some topical medications possess a duration of action comparable to the oral dosage forms. Oxymetazoline, for example, is reported to be active for 6 to 12 hours after administration.

The orally administered drugs rarely cause rebound congestion and, therefore, may be preferred when a decongestant is needed for longer than 3 to 5 days. Another claimed advantage is that the oral agents represent a uniform dose and are not reliant on the dexterity of the person using the application utensil, the amount of solution left in the spray bottle, or the viscosity of the solution. Some proponents of oral dosage forms feel that they prevent cross contamination between different users, or reinfection of the same person due to touching the applicator, inhaler or plastic spray tip to the nasal area and picking up infecting organisms.

Systemic drug products may cause side effects not experienced with topical agents because the systemics affect tissues other than those of the nasal mucosa. Also, topically applied decongestants induce a more prompt and profound vasoconstriction of nasal blood vessels than oral agents. This accounts for their absorption being negligible. Thus, systemic reactions following topically applied nasal decongestants are rare when these products are used as directed. However, when an excessive amount of decongestant solution is placed into the nose, it drains into the stomach where it can be absorbed. Most clinical symptoms originating from topical decongestant use are caused when the drugs are overused.

Consumer Advice For Topical Decongestants

The correct use of the applicator utensil is most important. As a rule, a nasal spray is preferred over drops because it delivers the medication dispersed into a finer particle size which will penetrate a greater area of the nasal mucosa. The medication is less likely to be swallowed because the particles are smaller and do not flow backward as rapidly. On the average, a single spray will deliver the equivalent of three drops.

Absorption can be minimized when using a spray by keeping the head upright during and after administration. For the next few minutes, the person should sniff hard. This will allow additional medication to reach further into the nose if congestion still persists. Keeping the head upright will permit excessive drug to run out of

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Nasal Decongestants

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the nose instead of into the throat and then into the stomach.

When using drops, the individual should recline on a bed with his head hanging over the edge. He should remain there for several minutes after the drops have been instilled. Turning the head from side to side helps distribute the medication to a larger area of the nasal mucosa.

For optimal action, inhalers should be warmed in the hand before use. This increases the volatility of the active ingredient and its chance of reaching the affected nasal mucosa. The end of the inhaler should be wiped clean after each use and the unit should not be shared with other patients.

It is a good idea to keep all medication out of the reach of children, but this is especially important for inhalers. Neither levodesoxyephedrine nor propylhexedrine has been found to be safe for use in children under the age of six. If a child swallows an inhaler wick, systemic effects are possible because the active ingredient will be released in the gastrointestinal tract and will be absorbed.

The Use of Decongestants in Children. Only nasal decongestants with specific indications and dosage instructions for such use should be administered to children. Drops are generally preferred for children under the age of six because their nostrils are too small to accommodate the spray tip. Also, they will hold still better for the application of drops than for a spray.

Mentholated products are usually safe for adults but their use in children under the age of two should be avoided. In infants and small children, menthol-containing products can cause spasms of the glottis. Asphyxiation has been reported in infants following topical applications of menthol-containing preparations.

Contamination. Containers of topical nasal decongestants can become contaminated with bacteria or viruses after improper use. This is minimized if the dropper or spray tip does not touch the nasal passage. If this is not possible, the dropper or spray tip should be rinsed in hot water

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after each use. Needless to say, no more than one person should be permitted to use the same container. The bottle or spray pack should be discarded after the medication is no longer needed. It should also be discarded if the solution becomes discolored or outdated. The product should be stored in a cool place, since this will retard the growth of organisms inadvertently introduced into the container.

TABLE 3
Basic Consumer Advice for Nasal Decongestants

Topical Products

- Do not use this product for longer than 3 to 5 days unless a physician directs otherwise.
- This product should only be used by one family member, to minimize the chance for contamination.
- Do not administer to children under the age specifically noted on the label.
- Keep this medication out of reach of children.
- Keep this product tightly closed and in its original container. Do not refill spray containers from a stock package.
- Do not touch the nose or other tissue areas with the spray tip or dropper.
- Do not use this product if the solution has turned brown, or developed an odor.
- A drop form is preferred over a spray for children, due to their small nasal openings.
- Do not exceed recommended dosage. To do so may cause symptoms such as sneezing, burning, stinging, or an increase in nasal discharge.

Systemic Medication

- Do not exceed recommended doses in order to avoid symptoms such as nervousness, dizziness, and sleeplessness.
- If symptoms persist longer than seven days, get worse, or are accompanied by a high fever, consult a physician before continuing use.
- Do not take this preparation if you have high blood pressure, diabetes, heart disease or thyroid disease except under the advice and supervision of a physician.
- Do not take this preparation if you are presently taking a prescribed antihypertensive and antidepressant drug containing a monoamine oxidase inhibitor, except under the advice and supervision of a physician.

Summary

Used correctly, nasal decongestants are safe and effective for self-medication in alleviating mild nasal congestion (stuffy nose). The FDA Advisory Panel on OTC Decongestants has published consumer advice for their proper use. It is summarized in Table 3.

Please turn to
Correspondence Course Quiz on Page 32.

STATE HMOs DRAW ABOUT 25 PERCENT

RALEIGH — Almost one-fourth of the state employees eligible to sign up for one of the new health maintenance programs did so last month in the initial phase of a new health care program offered to state employees, teachers and retirees, the N.C. Department of Insurance said.

More than 40,000 current or retired state employees have signed up for one of three HMOs available to them, according to insurance department statistics. About 175,000 state employees, teachers and retirees in 48 counties had until May 23 to select one of the HMO plans or remain with the current state health plan.

An HMO provides medical care for a fixed monthly payment, using either its own staff or doctors and other health professionals under contract.

As of June 6, the Blue Cross and Blue Shield of North Carolina Personal Care Plan had signed up 37,137 current or retired state employees, the insurance department said. The Kaiser Foundation Health Plan of North Carolina had 1,349, and Prudential Health Care Plan Inc. had 1,803.

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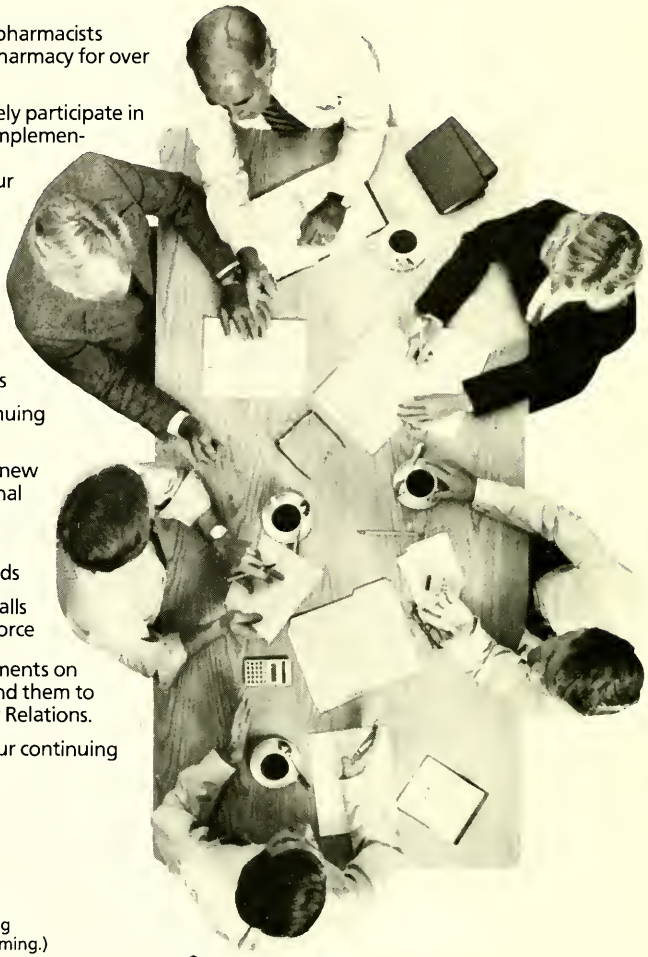

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September 11, 1986 — Smoking Cessation, sponsored by Merrell Dow

October 9, 1986 — New Drugs 1985-1986.

November 13, 1986 — Eye Care & Contact Lens Products

The meetings are held the second Thursday of the month at Charlotte Memorial Hospital auditorium, at 7:00 pm. Each program is worth two hours CE credit, and additional ACPE approval is being sought for these programs.

HENDERSON

Recently installed officers of the Four County Pharmaceutical Association (Vance, Granville, Warren and Franklin) are: J.B. Clay, Oxford, President; John C. Stancil, Henderson, First Vice President; Morris Hedgepeth, Henderson, Second Vice President; Charles Creech, Oxford, Secretary Treasurer; and Directors Linda Blackburn, Macon, Ted Gupton, Louisburg, Sholar Powell, Henderson and Dallas Evans, Oxford.

HILLSBOROUGH

A Chatham County man was arrested Monday, April 28, 1986, after trying to rob Revco Discount Drug Store at gunpoint and holding a pharmacist hostage for 15 minutes. The man entered the store, took the pharmacist hostage and demanded drugs. When police arrived, the robber backed out of the store with the hostage and was arrested when he apparently tripped and fell.

CARRBORO

Police are searching for a man who robbed Vaughn Independent Pharmacy of an undisclosed quantity of Schedule II controlled drugs Thursday afternoon, June 19, 1986. The man reportedly has a pistol under his coat and demanded the drugs from the pharmacist. The robber fled the area on foot after obtaining the drugs.

DURHAM

Durham Drug Company was destroyed by a Saturday night fire, June 28, believed to have been started by lightning. Firemen were called to the scene about 11:30 pm because of flames leaping 20 feet in the air from a manhole in front of the store. Soon flames burst through the roof of the building which was totally gutted, as was an empty store next door.

PHARMACEUTICAL DATA SERVICES REPORTS that prescriptions were essentially unchanged for December 1985, compared to the same month a year ago. PDS Reports that 1985 was a year of no growth for prescription drugs in the United States. Approximately 1.5 billion total retail prescriptions were dispensed in 1985; down - 0.3 percent when compared to 1984. Consumers were responsible for $14.7 billion in U.S. retail sales at acquisition cost for prescription medication.

CHARLOTTE

The Charlotte Woman's Pharmaceutical Auxiliary held its regular meeting Tuesday, April 8th, at the Y.W.C.A. with Mrs. Jesse Oxendine, president, presiding. Mrs. Douglas Corwin gave the devotional, which was followed by a buffet luncheon.

Reports were given by Auxiliary Board members and the standing committees. Mrs. Don Smith presented the following slate of officers for 1986-87:

President
Mary Lou Davis (Mrs. Leslie)
1st Vice President
Marguerite Bennick (Mrs. Johnie)
2nd Vice President
Nancy Hawfield (Mrs. W.B.)
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Virginia Steele (Mrs. T.K.)
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Historian
Laura Cannon (Mrs. C.L.)
Parliamentarian
Marguerite Colina (Mrs. Gilbert)
Advisor
Jewell Oxendine (Mrs. Jesse)

Plans for attending the North Carolina Pharmaceutical Convention in Greensboro were discussed.

Door prizes were won by Mary Lou Davis, Marguerite Bennick, "Pick" Williams, Laura Cannon, Lurlene Barnhardt, and Virginia Steele.

Virginia Steele
Corresponding Secretary

CORRESPONDENCE COURSE QUIZ

Nasal Decongestants

1. The endogenous agent that is most responsible for causing an inflammatory response in the nose and resulting congestion is:
   a. acetylcholine.
   b. epinephrine.
   c. histamine.
   d. serotonin.
2. Which of the following is LEAST likely to be an effective nasal decongestant when applied topically?
   a. Levodesoxyephedrine
   b. Phenylephrine
   c. Phenylpropanolamine
   d. Propylhexedrine
3. Manufacturers of systemic nasal decongestants must place a warning on the labeling of their products advising against use without the advice of a physician, if the consumer has any of the following diseases with the EXCEPTION of:
   a. asthma.
   b. diabetes.
   c. heart disease.
   d. high blood pressure.
4. Which of the following is the most appropriate nasal decongestant to recommend for a consumer with any of the three disease states that the warning referred to in question #3?
   a. Afrin
   b. Afrinol
   c. Propagest
   d. Sudafed
5. Which of the following statements is true?
   a. Systemically administered decongestants have been proven to be safer and more effective than topical agents.
   b. The use of topical decongestants is neither contraindicated nor implicated in any interaction with other drugs.
   c. Topically administered decongestants have been proven to be safer and more effective than systemic agents.
   d. Orally administered decongestants induce a more prompt and profound nasal vasoconstriction than topicals.
6. The active ingredient in Novafed is:
   a. ephedrine.
   b. pseudoephedrine.
   c. levodesoxyephedrine.
   d. phenylpropanolamine.
7. The predominant cause of nasal congestion is:
   a. airborne pollutants.
   b. hay fever.
   c. noxious odors.
   d. the common cold.
8. The group of nasal decongestants that is LEAST likely to cause rebound congestion is the:
   a. long acting topicals.
   b. orally administered agents.
   c. short acting topicals.
9. Systemic nasal decongestants are most likely to inhibit the action of:
   a. Ismelin® and Hylorel®.
   b. Larodopa® and Aldomet®.
   c. Reserpine and Apresoline®.
   d. Wytensin® and Catapres®.
10. In order for the lungs to function properly, air delivered to them optimally should be at:
    a. 25% relative humidity.
    b. 50% relative humidity.
    c. 75% relative humidity.
    d. 100% relative humidity.
11. Pharmacologically, nasal decongestants:
    a. stimulate beta-adrenegic receptors.
    b. inhibit H_1 receptors.
    c. stimulate alpha-adrenergic receptors.
    d. inhibit H_2 receptors.
12. The most predominant CNS effect of nasal decongestant is:
    a. depression.
    b. stimulation.
13. The preferred dosage form for topically applied nasal decongestants in infants is:
    a. drops.
    b. spray.
14. Nasal decongestants are:
    a. anticholinergics.
    b. antihistamines.
    c. sympatholytics.
    d. sympathomimetics.
15. A consumer requesting a topical nasal decongestant with the longest duration of action should be advised of a product containing:
    a. ephedrine.
    b. naphazoline.
    c. oxymetazoline.
    d. pseudoephedrine.

1986 Elections Committee Report

The NCPhA Elections Committee met June 25, 1986, at the Institute of Pharmacy in Chapel Hill to open and tally the ballots cast in the mail election. The results are as follows:

For NCPhA First Vice President (President Elect) ..... Albert F. Lockamy, Raleigh
For NCPhA Second Vice President ..... W. Robert Bizzell, Kinston
For NCPhA Third Vice President ..... Loni T. Garcia, Lumberton
For NCPhA Executive Committee (One Year Term) ..... Betty H. Dennis, Chapel Hill
Claude U. Paoloni, Chapel Hill
Donald V. Peterson, Durham

Congratulations to each successful candidate. You will be installed in your respective office at the 1987 Annual Convention of the North Carolina Pharmaceutical Association in Charlotte next April. Several of the contests were close and those who did not win made a respectable showing.

The Elections Committee hereby certifies the above persons as having been duly elected, to be installed as prescribed by the Constitution and Bylaws of the Association.

Respectfully submitted
The Elections Committee

LeRoy D.Werley, Jr.
J. Keith Caviness
Linda L. Butler
Robert L. Smith

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- NCPhA will maintain a record of your completed CE credit hours. Upon successful completion of each program you shall receive a certificate for one hour of Board approved CE.
- If the answers to more than two questions are incorrect, the questionnaire will not be acceptable for CE credit. If your questionnaire is not accepted you will be notified within 10 days and given an opportunity to submit a second questionnaire.

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3. a b c d	*6. a b c d*	*9. a b c d*	*12. a b c d*	*15. a b c d*

Evaluation ☐ Excellent ☐ Good ☐ Fair ☐ Poor

How long did it take you to read the article and complete the exam? _____

STUART PHARMACEUTICALS SUPPORTS MEDIC ALERT FOUNDATION BY UNDERWRITING MAJOR PUBLIC EDUCATION PROGRAM THROUGH PHARMACIES

A national program underwritten by Stuart Pharmaceuticals that will establish the nation's pharmacies as a vital link in the Medic Alert emergency medical communications network was unveiled at the recent annual meeting of the American Pharmaceutical Association.

Called "Dispense a Prescription for Life," the program is a collaboration of the National Pharmacy Task Group and the Medic Alert Foundation International to enlist the nation's 55,000 pharmacies in efforts to enroll patients with life-threatening health problems in the Medic Alert emergency medical information network.

Medic Alert is the only nonprofit organization solely devoted to providing a professional emergency medical identification service for people with conditions that could put them at risk in emergency situations. Components including a Medic Alert Emblem (bracelet or necklace), wallet card, and emergency hotline provide care givers the medical information they need to make proper, lifesaving decisions in emergency situations.

"Because of the potential seen in establishing a cooperative program between pharmacists and Medic Alert, the National Pharmacy Task Group, composed of leading chain and community pharmacists and a representative of Stuart Pharmaceuticals, was recently created to develop a program through which pharmacists can meaningfully address their patients' emergency care needs and build patient loyalty," says Robert Johnson, Executive Vice President of the California Pharmacists Association and Chairman of the National Pharmacy Task Group. "Studies show that every day, more than 13,000 emergency room cases in this country are complicated by lack of up-to-date, reliable medical information. By recommending Medic Alert's service, pharmacists can have a positive influence on the lives and health of their patients."

In a recent survey of Medic Alert members, three percent reported that "it saved my life," 21% reported learning from medical professionals that it "saved time in emergency treatment", 20% said it "assisted in accurate diagnosis," and 75% suggested that it gave their families "peace of mind."

"The role of the pharmacist in the Medic Alert system reflects a growing trend in patient care as pharmacists are being consulted more and more by patients about health care problems," according to Richard Haggard, National Field Director for Medic Alert. "The pharmacist's accessibility, combined with his or her awareness of the patient's drug regimen, provides a highly effective avenue for identifying those patients most likely to benefit from Medic Alert membership and encouraging them to participate in the program. Medic Alert is pleased that Stuart Pharmaceuticals has provided this grant to assist in making this vital emergency medical service available through the nation's pharmacists."

Most of the Stuart grant will go towards production and distribution of the National Pharmacy Kit—a graphically coordinated package specifically designed for use by pharmacists, including a front window poster, counter holders for applications, two Medic Alert Reference Guides, stuffers to be inserted in prescription packets of membership candidates, and pharmacist's response cards. Extra copies of the National Pharmacy Kit will be available to pharmacies on request through Stuart Pharmaceuticals representatives.

DEATHS

Ernest William Rollins, Sr., 83, Winston Salem died Monday June 2 after several weeks of illness. A graduate of Medical College of South Carolina he established and organized the pharmacy department at N.C. Baptist Hospital where he served as Director for nearly 40 years. He served as president of the Forsyth County Pharmaceutical Society, the N.C. Society of Hospital Pharmacists and of the Southeastern Society of Hospital Pharmacists. He was named Hospital Pharmacist of the Year in North Carolina in 1963 by the Society.

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STAFF PHARMACIST

North Carolina Baptist Hospital, a 701-bed facility affiliated with Bowman Gray School of Medicine, has opening in the Satellite Pharmacy. The pharmacy offers unit dose, nutrition support service, clinical services, and a drug information service. Winston-Salem is located in the beautiful Piedmont section of North Carolina with beaches and mountains no more than an afternoon's drive. Winston-Salem's cultural attractions include presentations by the North Carolina School of the Arts, Piedmont Chamber Orchestra, Winston-Salem Symphony and N.C. Dance Theatre. For more information, send resume or call collect: Letha Huffman N.C. Baptist Hospital, 300 S. Hawthorne Rd. Winston-Salem, NC 27103. 919-748-4717.

ASSISTANT DIRECTOR OF PHARMACY: interviews are now being held with qualified professionals for this position. Successful candidate will report directly to the Director of Pharmacy. Licensure to practice as registered pharmacist in North Carolina required. We offer an excellent compensation and benefit package. Interested and qualified professionals may contact: Highsmith-Rainey Memorial Hospital, Personnel Office, 150 Robeson St., Fayetteville NC 28301. (919) 483-7400 ext. 161. Affiliate of HCA. EOE M/F/H.

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Continued on page 36

APhA AMONG OLDEST NONPROFIT ORGANIZATIONS

The United States Pharmacopeial Convention and the American Pharmaceutical Association are among the oldest nonprofit organizations in the United States. This information wasn't found in Trivial Pursuit's "pharmacy" series (as far as we know, that one hasn't hit the shelves, yet) but, rather, was gleaned from a recent article in *Association Management,* the monthly journal of the American Society of Association Executives.

That article listed the top 100 nonprofit organizations in membership and staff size, the 100 youngest, and the 100 oldest.

Classifieds

Continued from page 35

POSITION AVAILABLE: EXECUTIVE DIRECTOR, STATE PHARMACISTS ASSOCIATION

Candidates are urged to submit their resume and a recent photograph for consideration by the search committee for the position of Executive Director of Kentucky Pharmacists Association. The Association is a statewide professional society of practicing pharmacists, consisting of over 1600 members and an annual budget in excess of $200,000. Responsibilities include management of the Association, and its subsidiary corporations in addition to public speaking, lobbying, liaison with related health care organzations and government agencies, publication of a monthly journal and newsletter, maintenance of an association headquarters building and supervision of a staff of 4½ full-time individuals. Qualified candidates should possess experience in association management or a closely related field and excellent oral and written communications skills. Employment is anticipated for August 15 or sooner at the discretion of the successful candidate. Submit resumes in confidence to: Search Committee, Kentucky Pharmacists Association, P. O. Box 715, Frankfort, KY 40602. Equal Opportunity Employer.

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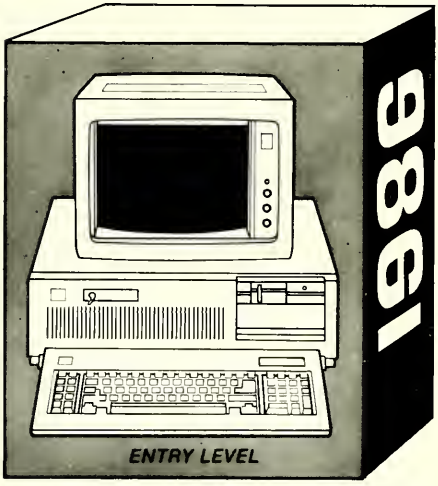

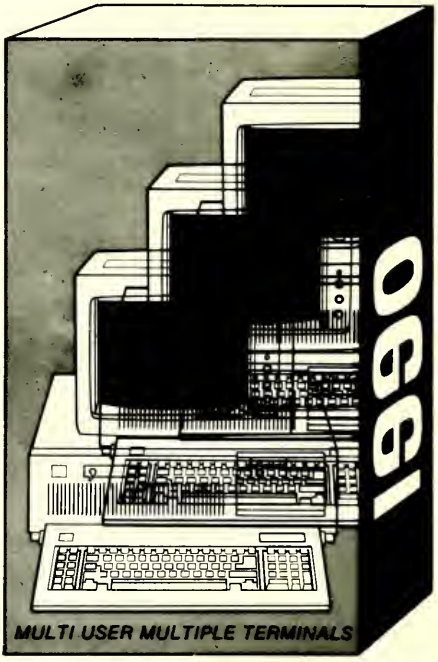

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1985–86 NCPHA President H. Shelton Brown, Jr., was pleasantly surprised when presented with his certificate of membership in the N.C. Academy of Pharmacy by Al Mebane at the annual convention in Greensboro.

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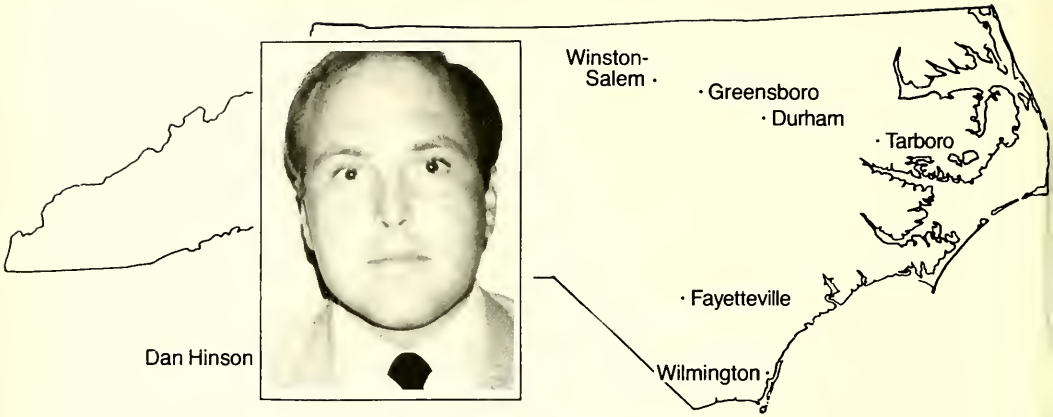

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PHARMACY BOARD EXEC LOOKS OUT FOR PUBLIC

by Sudie Taylor
Staff Writer
The Chapel Hill Newspaper

It is a coincidence, says David Work, that the N.C. Board of Pharmacy is located next door to a retail drug store in a Carrboro shopping center.

Yet, in a way the Willow Creek location serves as a visual reminder of the board's mission: protection of the public through the state licensing of pharmacists.

"We tend to the public health, safety and welfare," said Work, executive director of the N.C. Board of Pharmacy.

"We are not supposed to look after the interests of pharmacists; we are supposed to look after the public's interests."

Work, 46, for 10 years has served as executive director of six-member board. Work is himself both a pharmacist and an attorney.

This spring, Work was honored with a distinguished service award from the National Association of Boards of Pharmacy. Each state's pharmacy board, plus those in the Virgin Islands, Puerto Rico and several Canadian provinces belong to the national association.

The Iowa native has seen many changes in the pharmacy profession in his decade heading the North Carolina board.

Ten years ago, several of the state's counties lacked a pharmacist. Now, every county has at least one.

The state continues to experience a shortage of pharmacists, Work said.

"Right now there are jobs open in 50 (N.C.) cities," Work said.

That shortage may be relieved once Campbell University begins to graduate pharmacists. Currently, UNC has the only School of Pharmacy in the state. Campbell's pharmacy school is the first new pharmacy school in the United States in 35 years, Work said.

As of April, the latest figures available, North Carolina had 3,928 practicing in-state pharmacists. Thirty percent of those pharmacists are women, another trend Work has seen. More than 60 percent of UNC's School of Pharmacy is female.

"Pharmacy is a very good field for women," said Work, father of three daughters. "For instance, there's rewarding pay. It is clean work without a great deal of physical strength. There is a demand for it. There is plenty of parttime work available. And it is highly respected."

David R. Work

Work cited a Gallop poll of a year ago in which the public ranked pharmacists second only to ministers, but well above physicians, as the most highly respected professionals.

Part of Work's job is to keep that public respect intact through ensuring standards for the state's pharmacists. In two weeks, 150 candidates will take the licensing exam, given twice a year. There is both a national exam and a three-part practical exam which tests laboratory mixing skills, supervisory experience and state laws.

The state has a 90 percent passing rate on the exams.

To be licensed as a pharmacist, candidates must pass the exam and complete 1,500 hours experience.

The purpose of the exam is to check for minimum competency "to ensure they are safe to turn loose on the public," Work said. "It is not an achievement test."

Once pharmacists are out practicing it is the board's duty to see that high standards are maintained. As of January 1985, pharmacists were required to take continuing education courses at the state's nine Area Health Education Centers.

continued on page 6

continued from page 5

When pharmacists fail to do their job properly the board steps in. Citizens as well as doctors can complain to the board when, for example, a prescription is incorrectly filled. The board has three full-time investigators who study the complaints. The six-member board, of which five are licensed pharmacists, meets monthly to take action on those investigations and other issues. Last year, for example, the licenses of 37 pharmacists were suspended or revoked, which is less than one percent of those actively practicing.

Work's legal background helps with those proceedings. His father was a general practice attorney in his hometown of Clinton, Iowa. Work went to the University of Iowa College of Pharmacy and returned to his hometown to be the pharmacist at a community drug store.

At age 25, Work had a choice of buying the store or leaving town. He chose to move 1,000 miles west to attend the University of Denver College of Law.

Work was a corporate attorney for Blue Cross of Illinois in Chicago before coming to UNC as an assistant professor and then as assistant dean in the UNC School of Pharmacy.

Being an attorney and a pharmacist is both a help and a hindrance of sorts in his job, Work said.

"My law background makes my job easier to do, although I tend to see more problems than I would if I didn't have the background," Work said.

ELIZABETH AYERS HONORED

Elizabeth Ayers, Winston-Salem, has been initiated into Delta Omega, the National Honorary Public Health Society. She was recognized for academic excellence and leadership in public health studies. Libby received her master's degree in Public Health from the UNC at Chapel Hill School of Public Health this spring. She is employed at Forsyth Memorial Hospital.

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REPORT TO THE NORTH CAROLINA PHARMACEUTICAL ASSOCIATION

April, 1986

by Ronald W. Maddox, Pharm.D.
Professor and Dean
Campbell University School of Pharmacy

I. **Admissions**

The response to the school of pharmacy has been tremendous. We currently have 97 applications of which 50 have been accepted and paid a deposit to reserve their place in the charter class. We have another 7 students that have been accepted that have not reached their deposit due date. It is, also, noteworthy that 90% of our admissions are North Carolina residents, 60% are females, the overall grade point average is 3.2, and 28% have a B.S. degree.

II. **Accreditation**

An evaluation panel from the American Council on Pharmaceutical Education (ACPE) visited Campbell University School of Pharmacy in February. The evaluation panel was composed of Dr. Robert K. Chalmers, professor of pharmacy practice and head of the department, school of pharmacy and pharmacal science, Purdue University, and a member of the American Council on Pharmaceutical Education; Dr. Daniel A. Nona, executive director of the American Council on Pharmaceutical Education; Dr. Michael R. Ryan, dean of the college of pharmacy, University of Tennessee, Center for Health Sciences; and Dr. Lawrence C. Weaver, former dean of the college of pharmacy, University of Minnesota, and vice president of professional relations, Pharmaceutical Manufacturers Association, and Mr. William Randall, Jr., a member of the North Carolina Board of Pharmacy.

The evaluation panel gave the school of pharmacy a very positive report which included the following statement, "the evaluation panel believes that the five-year plan for the School of Pharmacy is feasible, and expresses its general confidence in the ability of the school of pharmacy to achieve its stated goals in compliance with ACPE standards."

III. **Faculty**

Effective January, 1986, Dr. Daniel Teat assumed the position of Director of Admissions and Continuing Education. Prior to coming to Campbell University, Dr. Teat was a clinical pharmacist and President of Clinicare Consultants of America. Dr. Teat has been involved in the promotion of clinical pharmacy services for eight years and brings a "real world" approach to the school of pharmacy.

Effective March, 1986, Dr. Harry Rosenberg assumed the chairmanship of the Department of Pharmaceutical Sciences. Prior to joining Campbell University, Dr. Rosenberg was a Professor of Biomedical Chemistry at the University of Nebraska Medical Center. Dr. Rosenberg brings experience with the doctor of pharmacy program at the University of Nebraska and excellent teaching credentials to Campbell University.

Two additional faculty members will be added by July, 1986. These individuals will fill positions in anatomy-physiology and biochemistry/immunology. These positions were advertised nationally and thirty applications have been received. We are currently interviewing select applicants for these positions.

In summary, the School of Pharmacy at Campbell University is a reality. The charter class is virtually filled. We have received an excellent report from the American Council on Pharmaceutical Education and the final faculty members for the first professional year are being interviewed.

Dean Ronald W. Maddox

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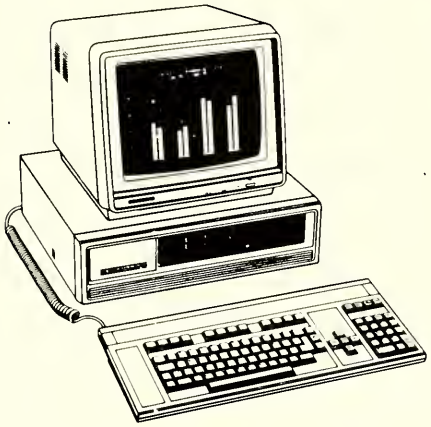

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PHARMACIST WINS SCHERING SWEEPSTAKES FOR TRIP TO LONDON

Sandra Nance, owner of Prescription Shopper in Chadbourn, North Carolina, will join 49 other pharmacists and their guests on a week-long trip to London in November for winning a sweepstakes promotion sponsored by Schering Corporation.

To become a winner, Nance, a pharmacist for 13 years, correctly answered the question, "What long-acting cold tablet do most pharmacists recommend?" which was posed to her by an unidentified bonded security agent acting as a customer. The correct answer, "Drixoral," based on a recent survey of American pharmacists, is one of Schering Corporation's leading over-the-counter medications.

Prescription Shopper was one of 55,000 pharmacies in this country to receive a sweepstakes entry form from Schering Corporation in April.

Every pharmacist who entered the contest was eligible to receive a visit from an undercover "VIP Shopper," who asked participating pharmacists, chosen at random, one of four questions. These included:

- What nasal spray do most pharmacists recommend?
  (Answer: Afrin)
- What allergy remedy do most pharmacists recommend?
  (Answer: Chlor-Trimeton)
- What do most pharmacists recommend for Athlete's Foot?
  (Answer: Tinactin)
- What long-acting cold tablet do most pharmacists recommend?
  (Answer: Drixoral)

Ten winners of Schering's "Very Important Pharmacist" Sweepstakes promotion have already been chosen, and another forty will be selected. The promotion is designed to reward pharmacists' knowledge of the number-one recommended OTC remedies, and to thank pharmacists for recognizing the quality and effectiveness of Schering's leading OTC products.

Nance has owned the Prescription Shopper, which her husband Larry manages, for the past five years. She said she hopes they can both get away for the trip, but if not, Nance will take her 16 year old daughter. Nance, who has never been out of the United States, is looking forward to traveling abroad. She said her winning answer came naturally because she customarily recommends Schering products.

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Reception 6:30 pm
Dinner 7:00 pm

Jack G. Watts of Burlington has been selected as the 1986 Pharmacist-of-the-Year by the North Carolina Pharmaceutical Association and will be honored at a dinner in Burlington, Friday night, September 5, 1986. You are cordially invited to attend the 40th Annual Mortar-and-Pestle Dinner and join us in recognizing this most deserving pharmacist.

The dinner will be held at the Alamance County Country Club in Burlington, and will begin at 7:00 pm. A 6:30 pm reception at the Country Club will precede dinner.

You may order dinner reservations by completing the form below. A block of rooms is being held at the Ramada Inn Burlington (I-85 and NC 62). Room reservations are being handled through NCPhA. Reservations for rooms will be taken until August 25, 1986. Maps will be sent with your confirmation cards and dinner reservations.

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DICKINSON'S PHARMACY

by Jim Dickinson

Of generics, liability and FDA. As the summer of '86 got under way, pharmacists could be excused if they felt more than their usual degree of confusion about legal issues. Consider the ingredients of such confusion:

(1) Anecdotal, gossipy "evidence" of the supposed inequivalence of some of the new generics increased, especially on the detailman network and in the lay media; FDA assurances couldn't be trusted.

(2) FDA increased its public countermeasures, demolishing the latest "real-life" clinical "evidence" of alleged generic chlorpromazine inequivalence in an Augusta (Ga.) hospital as a clumsily incompetent example of faulty observations.

(3) FDA's authority as the supreme standard-setter for drugs was itself demolished by a federal appeals court in Georgia, which found that FDA drug labeling on Ortho Gynol was not enough to exempt J&J from damages for failing to put additional wording on the product about unproven theoretical birth defects.

Until this case, federal — and most other — courts had usually deferred to FDA expertise (although they were never obliged to do so); the decision effectively demoted the agency from its unique status as a setter of optimal (risk-benefit) standards to run-of-the-mill regulatory status as a setter of minimal standards, subject like any other agency to everyday court oversight. In fact, the Georgia court equated drug risks with automobile risks, applying a precedent involving Honda Motor Company as a corporation with products comparable to Ortho's.

(4) Pharmacy continued to digest the implications of June's *Riff v. Morgan Pharmacy* case, which saddled the profession with a "you are your brother's keeper" duty to second-guess prescribing practices. The question hangs heavy: How much help can FDA determinations be, in such second-guessing, especially with physicians being encouraged to doubt the wisdom of generic substitution?

(5) The marketing of pharmaceutical service administrative organizations (PSAOs), essential to the survival of independent pharmacy, was stepped-up, with troublesome drug utilization (DUR) obligations and the prospect of more confrontations with prescribers.

(6) As if to underscore this point, the July 11 issue of *JAMA* reported a major study showing that when DUR is used to individually educate physicians about prescribing errors, one in three will correct their bad habits. That's a bottom-line that begs PSAOs to sell their DUR capabilities to third-parties as a way of reducing the waste in iatrogenic hospital stays.

But do PSAOs really have DUR capabilities? Do independent pharmacists want to be involved in such things? At least one PSAO has told me that it is having a hard time selling its members on DUR (which, of course, requires computer capability in the pharmacy).

If chains and mail-order competitors of independents are not doing DUR, why should PSAOs jump in?

And to throw yet another confusing ingredient into this chaos, what about dispensing physicians? They're part of DUR! At the Alabama Pharmaceutical Association's annual meeting in July, I was asked to stretch my imagination on this problem and, caught off-guard, I blurted out that I thought pharmacists should snitch to the patients about the conflict-of-interest issue.

Later, as my airplane took me home, further thought refined that advice to a simple message that pharmacists could convey to patients generally, perhaps on a display board: "Two heads are better than one, and doctors do make mistakes; this pharmacy corrects (xx) prescribing errors each week."

Isn't this what *Riff v. Morgan Pharmacy* is driving at? If physicians and pharmacists don't accept the "brother's keeper" role, both professions will suffer — as will the public, through lesser standards or care, and higher costs of covering needless mistakes.

And, anyway, isn't this what PSAOs are trying to sell to third-party programs? And isn't it something that chains and mail-order houses aren't likely to promote that they do?

It's a practical byproduct of DUR. It's something that you can do for yourself, as your own authority, without having to rely on FDA for backup. Maybe it's also survival.

This feature is presented on a grant from Mylan Pharmaceuticals, in the interests of promoting the open discussion of professional issues in pharmacy. Mylan Pharmaceuticals accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of Mylan Pharmaceuticals.

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CALL FOR PAPERS

The NCSHP Program Committee is calling for papers to be presented in poster format at the Winter Meeting in Charlotte, February 5, 1987. Summaries of papers should be prepared according to the guidelines outlined in the January 1986 issue of *American Journal of Hospital Pharmacy* and submitted to Dennis Williams, Program Committee Chairman, Beard Hall 200H, UNC, Chapel Hill, NC 27514.

The deadline for receipt of papers is December 1, 1986. Notification of acceptance will be sent by December 22, 1986.

Papers submitted for presentation at national meetings are welcome. Please participate and share your work with your North Carolina Colleagues.

A Research Recognition Award, sponsored by the Upjohn Company, will be initiated at this meeting as well. A cash award will be presented for the best paper submitted. Each paper will be evaluated by at least two NCSHP members. Papers submitted for consideration of this award do not necessarily have to be presented at the poster session, but the author should clearly state his(her) intent upon submission.

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MedicAlert: THE PHARMACIST CAN MAKE THE DIFFERENCE

The National Pharmacy Task Group, in collaboration with Medic Alert Foundation, unveiled a pharmacist-to-patient education program featuring Medic Alert's service at the American Pharmaceutical Association's March Convention in San Francisco.

Because of the potential seen in establishing a cooperative program between pharmacists and Medic Alert, the National Pharmacy Task Group was recently created to develop a program through which pharmacists can expedite efficient emergency medical care, demonstrate that their care protects the health of their patients, and build patient loyalty, all at no cost to the pharmacist. By recommending Medic Alert's service, pharmacists can have a positive influence on the lives and health of their patients.

Medic Alert is the only nonprofit organization solely devoted to providing a professional emergency medical identification service for people with conditions that could put them at risk in emergency situations.

A series of 1985 surveys and research projects demonstrate clearly that Medic Alert aids cost-effective patient treatment. Today, Medic Alert is the only internationally recognized emergency medical data system that provides busy emergency personnel with vital patient information quickly, accurately, in one place and on time.

Survey and research information show that:

- One in four Americans has a medical condition that should be immediately known in an emergency.
- Over 13,000 emergency room cases every day in this country are complicated by a lack of accurate and accessible medical information.
- Over 95% of physicians who know Medic Alert say it can save lives.
- 3% of Medic Alert members say their lives have been saved by Medic Alert.
- 21% of members reported learning from medical professionals that Medic Alert service saved time in emergency room treatment.
- 20% reported learning from medical professionals that Medic Alert assisted in accurate diagnosis.

While various competitors have bracelets, cards and micro fiche, no other organization provides the world-wide comprehensive health protection system that Medic Alert provides

The Medic Alert **Emblem** (bracelet or necklace) is the TRIGGER that activates the emergency medical information system. Anywhere in the world, anytime of the day or night, medical personnel need only call Medic Alert's **24-hour hotline** and provide a patient's I.D. number engraved on the emblem. Within 30 seconds, information from the **computerized emergency medical file** can be provided to assist in treatment. In addition, each member has a **wallet card** and the Foundation initiates an annual update procedure. Members, however, can update information at any time.

The National Task Group during its special session presentation at the Convention emphasized that Medic Alert integrates the full circle of medical protection encompassing the patient, physician, hospital and pharmacist. Moreover, Medic Alert has developed special materials for the pharmacist and provides them at no cost upon request. The kit include:

1. Front window poster (full cover) to announce your pharmacy's involvement in this program.
2. Counter application holder with applications to be permanently placed for convenience of the patient near point of sale.
3. Medic Alert Reference Guides (2)
   - One to be posted in the work area to highlight conditions covered by Medic Alert protection
   - One to be placed at the point of sale for your staff and patients.
4. Stuffers to be inserted into all prescriptions bags for patients you believe could benefit from Medic Alert protection or to be used as a shelf taker.
5. Response card to be returned indicating participation in the pharmacist's program and ordering additional materials.

The materials for this project are underwritten by a grant from Stuart Pharmaceuticals, Division of ICI Americas Inc.

These new pharmacy materials have been mailed to all pharmacies. If you have not received your materials, please call Medic Alert Foundation International's Field Services Division, 1-800-344-3226 (In Alaska call 1-209-668-3333.)

No one has documented the mountains in wintertime more beautifully than watercolorist Joe Miller. His work has shown in art galleries far and wide, attracting comment for their witty titles while establishing Miller's impressive reputation in the field.

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CORRESPONDENCE COURSE

COUNSELING CONSUMERS ON OTC DANDRUFF REMEDIES

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University, Ada, OH
and
J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati, Cincinnati, OH

Goals

The goals of this lesson are to:

1. review the etiology and treatment of dandruff and seborrhea;
2. discuss the pharmacology of drugs that treat them.

Objectives

At the completion of the lesson, the successful participant will be able to:

1. recognize effective OTC therapeutic agents for the treatment of dandruff and seborrhea;
2. explain the proper technique for applying the discussed agents;
3. decide when the patient should be referred to a physician.

Most Americans have experienced at least one bout of dandruff and/or seborrhea sometime during their lifetime. Dandruff is the more common condition of the two, affecting an estimated 70 percent of the population. About 12 million Americans have experienced seborrhea. The potential magnitude of the market is further emphasized when one listens to or reads the advertisements of commercial products claimed to control these conditions. Dandruff and seborrhea can be safely and effectively self-medicated. But the precise cause of both conditions is not known. Therefore, some OTC remedies can offer little more than temporary relief of symptoms. In the minds of many consumers, however, relief of symptoms is satisfactory.

This month's article examines dandruff and seborrhea from a pharmacist's perspective. It reviews proposed etiologies for both conditions, and explains how pharmacists can distinguish between them. It also presents the proposed actions of OTC products which are intended to modify these conditions. Most importantly, it summarizes important information for consumers so they will receive maximal benefit from these products.

Background

The skin is composed of two major layers, the dermis and epidermis. The dermis (inner layer) contains a rich supply of blood vessels that brings nutrients to all the skin layers. The epidermis ("epi" outer) is comprised of two major strata, neither of which has its own blood supply. The basal (lower) level of the epidermal cells lies directly on top of the dermis and is, therefore, well supplied with its nutritional needs by fluids that diffuse upward from the dermis. The outer layer is not so supplied.

The cells that comprise the epidermis are continually formed in the basal level. They eventually migrate upward toward the skin's surface. They die and become dehydrated as they approach the surface because there is insufficient nutrition to maintain their functions. These highly compacted, dead, and dry cells are known

continued on page 19

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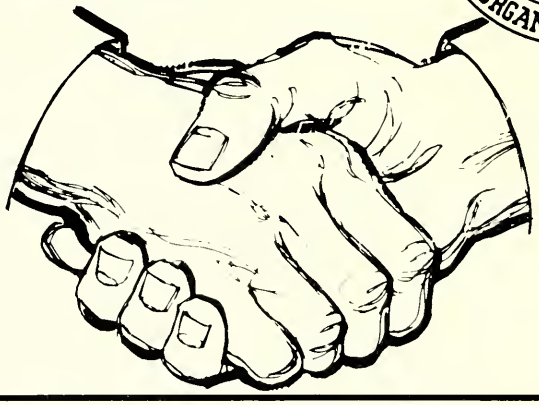

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Correspondence Course

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as the **keratin** (stratum corneum) layer. As a result of the skin's normal "wear and tear," the outermost dead epithelial cells slough off and are replaced by new cells from underneath. The process is continuous, usually requiring about 14 days from the time of formation. The sloughing process is usually imperceptible since the cells are normally shed individually, rather than in groups.

Dandruff and seborrhea share the same underlying bothersome symptom — an excess epidermal shedding rate. Since the cells are lost in relatively large clumps (scales), both conditions *are* perceivable.

Dandruff

Dandruff is defined as a chronic, non-inflammatory condition. It is characterized by excessive shedding of epidermal tissue lost in large clumps or scales that are dry, and appear white or grayish. On the skin, the condition is most commonly seen as small, round patches especially on the crown of the head. The sites occasionally itch. When excessive itching is present, a different dermatitis-related condition is most likely to be present.

Cause. The exact cause of dandruff is not known. Dandruff *per se* is not a disease. It is a symptom of some other disorder. Poor hygiene does not cause dandruff, but it may worsen an existing condition. Most experts agree that dandruff occurs because of a greatly increased rate of epidermal cell turnover. This rate is intensified to the point that the new cells do not have time for complete keratinization, and, consequently, they are shed *en masse*. Proposed, but as yet unproven, theories relate dandruff to improper diet, hormone imbalance, or to a deficiency of various vitamins.

Many years ago observers discovered the presence of a yeast microorganism on the scalp of persons with dandruff. This yeast was thought to be the cause of dandruff and a few references still state with authority that this is indeed the case. This microorganism has been identified as *Pityrosporum ovale,* but has been discounted as a cause of dandruff. *P. ovale* can be found in similar concentrations on the scalps of persons without dandruff.

Other microorganisms have also been identified as potential causes of dandruff. At present, however, none has been proven. It is interesting to note that one organism, *Propionibacterium acnes* (a common cause of acne), is found in lower conentrations on the scalps of individuals with dandruff. Whether or not this microorganism is linked to dandruff is also not known at this time.

Symptoms and Occurrence. Scaling of large clumps of cells called **squamae** is the one universally visible symptoms of dandruff. Usually the flaking is seasonal, occurring most frequently from October to December. Its occurrence and intensity decrease through the spring months and are least common during the summer. This modulation probably reflects seasonal humidity changes. When the humidity is low, dandruff is worse. As the humidity increases, dandruff becomes less of a problem. Dandruff exhibits several other characteristics summarized in Table 1.

continued on page 20

TABLE 1
Important Characteristics of Dandruff and Seborrhea

Characteristic	Dandruff	Seborrhea
Site	Scalp	See Table 2
Borders	Indistinct	Indistinct
Inflammation (redness)	No	Yes
Appearance of scales	Dry, grayish-white	Greasy
Age of onset	Puberty	Puberty
Itching	Variable	Usual
External factors that worsen condition	Cold weather	Stress, poor health
Rate of epidermal turnover	Twice the normal rate	More than twice the normal rate
Duration	Can persist for life, diminishing in middle and old age	Can persist for life, frequent exacerbation and remissions

Correspondence Course

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Dandruff is rare in youngsters under age ten. It generally begins with puberty, peaking in the early twenties. By middle and old age, its incidence declines; it is rare in geriatrics. Men and women develop it to the same extent.

Seborrhea

Seborrhea (seborrheic dermatitis), like dandruff, is characterized by an increased rate of epithelial cell turnover. While dandruff is almost entirely localized to the scalp, seborrhea may occur on any hairy or skinfold area of the body. Its most common site, however, is the scalp (*seborrheic capitus*). Other locations are listed in Table 2. These areas contain the highest concentration of sebaceous glands.

TABLE 2
Usual Sites for Seborrhea

Armpits
Back area between shoulder blades
Behind the ears
External ear canal
Eyebrows and eyelashes
Midchest
Nasal folds
Pubic area and groin
Scalp

Causes. Numerous theories for the cause of seborrhea have been advanced over the years. None of them fully explain all aspects of the disorder, and whatever it is that initially triggers the process remains a mystery.

According to the most frequently quoted theory, excessive sebum secretion provides a rich, oily, nutritional source for bacteria and yeast. These, then, convert this sebum to irritating substances (e.g., free fatty acids) that incite the local reaction and cause the symptoms. But while the term "seborrhea" describes excessive sebum

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flow, it still has not been shown that all persons with the condition have increased sebum production. In fact, carefully controlled studies have established that patients with the disorder frequently display sebum production characteristics that do not differ from their age-related counterparts who do not exhibit seborrhea.

The condition has also been linked to yeast and bacteria. For example, *Candida albicans* organisms are present in significantly higher numbers in infants with cradle cap. *Pityrosporum ovale* and *Staphylococcus aureus* are found in higher than normal concentrations in patients with seborrhea. However, the concentration of *Propionibacterium acnes* is more depressed in persons with seborrhea, than in persons with dandruff.

Like dandruff, seborrhea has also been linked to food allergies, vitamin B complex deficiency, immunological deficiency states, and to changes in the weather. The exact role that each of these factors contributes, if any, has not yet been determined.

Symptoms and Occurrence. The symptoms of seborrhea resemble those of dandruff in several ways (see Table 1). However, it is important to remember that the two conditions differ considerably. Seborrhea produces dull, yellowish-red lesions that are generally localized to one or a few areas of the scalp or other hairy surface. On occasion, larger areas may be affected. Common sites include the face, behind the ears, and upper trunk. These areas produce the most sebum and contain high levels of surface fats. Unlike with dandruff, itching is common in seborrhea.

Whereas dandruff occurs at a relatively stable level, seborrhea bouts vary in time and in intensity. They can be severe one time, mild the next, then more severe than the first bout on the next occurrence. Many people report that during periods of stress seborrhea appears or flares up. It is also characterized by inflammation and crusting, and may involve the eyebrows and eyelashes and cause blepharitis (inflammation of the eyelids).

Seborrhea is most commonly seen in middle-aged individuals and the elderly. Women are affected more frequently than men.

Seborrhea is also more common in patients with parkinsonism because these people have enhanced sebum secretion. When the tremors are controlled with medication, seborrhea improves markedly.

Cradle Cap. Cradle cap represents an infantile version of seborrhea. It normally involves the scalp, and the skin behind the ears, under the nose, and on the armpits, diaper area, and umbilicus. When it appears on the scalp, it usually occurs within the first couple weeks of life.

The condition results from accumulation of keratin and dirt on the baby's scalp and skin. Oftentimes the child's mother is hesitant to wash the scalp area well, fearing that permanent injury will result from applying pressure to the "soft spots" on the baby's head. This is, of course, an unfounded fear.

The condition normally clears within a month after birth and does not recur. On rare occasions it may evolve into a generalized itching dermatitis, and spread to the forehead, cheeks, and extremities. Except for those severe cases, cradle cap can be largely controlled by careful and thorough washing of the baby's scalp with water and ordinary soap. No special cleansing agent is necessary.

* * * * *

Treatment of Dandruff and Seborrhea

Treatment of both conditions is aimed at controlling the symptoms. Regular use of OTC remedies can be quite effective for this purpose. There are no known "cures." The action of most OTC products is based on the principle that if the large clumps of scales can be reduced in size, they will be less visible, and hence, the dandruff condition will be "controlled." Regular washing of the hair and scalp will help greatly. While this can be done daily, washing once every second or third day is frequently sufficient, except in severe cases.

Table 3 lists the therapeutic categories and representative OTC products that are marketed. These categories were reviewed by FDA's Advisory Panel on Miscellaneous OTC External Drug Products. The panel's recommendations are listed in the table and are discussed below.

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Correspondence Course

continued from page 21

TABLE 3
Dandruff/Seborrhea Remedies Containing Ingredients Ruled to be Safe and Effective by the FDA Advisory Panel

A.	**Coal Tar Derivatives**	(Shampoos)
	Alma Ter	Pentrax
	Denorex	Polytar
	DHS Tar	Psorex
	Estar	Tegrin
	Iocon	Tersa-Tar
	Neutrogena T	Zetar
	Packer's Pine Tar	
B.	**Salicylic Acid**	
	Domerine	Sebisol
	Ionil	Sebucare
	P and S	Xseb
C.	**Selenium Sulfide**	
	Selsun Blue	Sul-Blue
D.	**Sulfur**	
	pHisoDan	Sulfur-8
	Sulfoam	Sulpho-Lac
E.	**Zinc Pyrithione**	
	Breck One	Head and Shoulders
	Danex	Zincon
F.	**Salicylic Acid/Sulfur Combinations**	
	Cuticura Anti-Dandruff	Metab
	Diasporal	Sebaveen
	Fostex	Sebex
	Glover's Medicated	Sebulex
	Klaron	Sebutone
		Vanseb

Antiseptics (antimicrobials) have long been employed to treat scalp disorders. Their use is based on the theory that microorganisms are a possible cause of these problems. Antiseptics used include benzalkonium chloride, diiodohydroxyquin and povidone iodine. Their value in OTC dandruff remedies is questionable since, as discussed earlier, the microbial-induced theory for dandruff and/or seborrhea is not proven, and secondary infection is rarely encountered.

Cytostatics (e.g., selenium sulfide, zinc pyrithione) offer a more direct means for controlling dandruff. They reduce the rate of cell growth, and because there are fewer cells formed in any given period of time, scaling is reduced. These agents significantly reduce epithelial turnover of cells not only on the scalp, but anywhere on the body where the agents come

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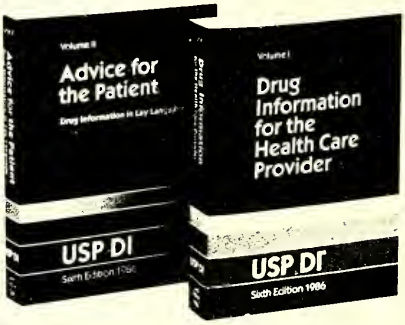

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into contact with them. Selenium sulfide has a direct depressant effect on cellular division; zinc pyrithione works nonspecifically as an epidermal cell toxicant. Some reports suggest that selenium sulfide acts more quickly than zinc pyrithione to control the condition. This has not been substantiated clinically.

Keratolytics cause the keratin layer to peel away, thus physically removing the scales. They probably act by dissolving the cement substance that bonds cells together. They do not dissolve keratin or prevent scales from forming. As the scales are loosened, they can be readily washed away.

Antipruritics are sometimes included in dandruff and seborrhea products because the sensations of pain and itching are transmitted by the same nerve fibers. Hydrocortisone has antipruritic, as well as antiinflammatory activity. However, dandruff is not an inflammatory condition. The OTC advisory panel recommended that temporary relief from itching does not effectively control dandruff or seborrhea. Therefore, its inclusion in OTC products intended for these uses will not be given final approval until additional data are gathered and analyzed.

Specific Suggestions of the FDA Advisory Panel

The list of ingredients in OTC antidandruff and antiseborrhea products reviewed by the FDA advisory panel is shown in Table 4. As can be seen from the table, only five agents were granted Category I (i.e., safe and effective) status. These include coal tar (formulated in shampoos only), salicylic acid, selenium sulfide, sulfur, and zinc pyrithione.

Coal Tar. This was shown to be safe and effective when used in shampoo form for treating dandruff and seborrhea of the scalp. Consumers should be reminded that coal tar may stain clothing, skin, and hair (especially gray, blond or bleached). Coal tar imparts a strong odor and should be thoroughly washed off before going out in public. Persons using a coal tar product should avoid excessive exposure to the sun or ultraviolet light for at least 24 hours after applying the product, since coal tar may also cause photosensitivity reactions.

Coal tar is suspected of causing cancer; chronic exposure to coal tar derivatives over several decades has been shown to be carcinogenic. The FDA advisory panel concluded that coal tar derivatives applied correctly to the scalp (e.g., 5 to 20 minutes maximum, 1 to 3 times weekly) were safe for short term self-administration for dandruff. However, since a preparation applied to the body to treat seborrhea may remain in contact with the skin for longer periods, additional studies to clarify coal tar's carcinogenic potential are needed. The panel recommended that coal tar products remain available OTC while these studies are underway. Paradoxically, FDA advisory panels that reviewed other types of OTC products advised that coal tar be removed from the OTC market.

Salicylic Acid. The advisory panel concluded that salicylic acid, in strengths of 1.8 to 3 percent, was an effective keratolytic to treat both dandruff and seborrhea.

Sulfur. In a concentration of 2 to 5 percent, sulfur is considered to be safe and effective for topical use. It acts as a keratolytic, similarly to salicylic acid.

Selenium Sulfide. Used in shampoos in a 1 percent concentration, selenium sulfide was ruled to be effective for controlling dandruff. The 2.5 percent product is restricted to prescription use. The advisory panel had no data to support the use of selenium sulfide for treating seborrhea.

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Specific Suggestions

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Used correctly, selenium sulfide is relatively nontoxic. While elemental selenium is quite toxic when ingested, there is little danger in absorbing toxic amounts when applied to intact skin. On broken skin (i.e., open lesions), the substance can be absorbed, and toxicity may occur.

Selenium sulfide has also been reported to discolor the hair. However, this does not appear to be a common occurrence. Individuals with dyed hair should test a small area with the shampoo to be certain no staining will occur. The shampoo should also be thoroughly rinsed off after use.

Zinc Pyrithione. Zinc pyrithione was concluded to be safe and effective for controlling dandruff and seborrhea. Concentrations recommended were 1 to 2 percent in shampoos, and 0.1 to 0.25 percent in other hairgroom products.

Consumer Advice

Specific consumer information has been discussed, but additional points on the use of dandruff or seborrhea products should be mentioned.

The hair and scalp should be washed with a regular shampoo prior to using the medicated product. This helps remove dirt and scales, and allows for enhanced penetration of the medicated product onto the scalp. Shampooing with a regular product may also be considered, following removal of the medicated product. This will help eliminate the objectionable odors and discoloring that some dandruff and seborrhea products impart to the hair and scalp. For mild dandruff, a non-medicated shampoo alone, used daily, should largely control the condition.

The medicated shampoo should be applied and left in place for the time specified on the label. A minimum period is 5 to 10 minutes. Massaging the scalp with a softbristle brush will assist in working the product down to the scalp.

CONGRATULATIONS TO

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On the new decor package in Buchanan's Drug Store, Greensboro. We are pleased to have been a part in executing this plan.

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Pharmacists should advise consumers to avoid contact of any OTC product for dandruff or seborrhea with the eyes or mucous membrances. If it occurs, the area should be thoroughly rinsed with water.

Selenium sulfide may impart oiliness to the scalp and, in some cases, worsen seborrhea. Its use for this condition should be limited to once every second or third day. If the scalp is especially oily, a product containing salicylic acid and/or sulfur may offer greater benefit.

OTC dandruff and seborrhea products work quite well for most people. However, if a product fails to provide relief from the condition, another product with different ingredients and mechanism of action should be tried. If the condition does not improve after a couple weeks, the individual should consult a physician. A more serious disease state may be present.

Unless otherwise indicated (i.e., for products intended to treat cradle cap), OTC products for dandruff and seborrhea should not be used on children under age two. This precaution is warranted because their skin surface in proportion to body weight is greater than that in adults. Furthermore, children do not have fully developed hepatic microsomal enzyme systems so they cannot handle potentially toxic substances that are absorbed.

To avoid possible damage to the eye, seborrheic conditions that involve the eyelids should only be treated by a physician.

TABLE 4
OTC Advisory Panel Categorization* of Dandruff/Seborrhea Ingredients

Ingredient	Dandruff	Uses
Alkyl isoquinolinium bromide	III	D
Allantoin	III	D,S
Benzalkonium chloride	III	D
Benzethonium chloride	III	D,C
Borate preparation	II	D,S
Captan	III	D
Chloroxylenol	III	D,S
Coal tar preparations	I, III*	D,S
Colloidal oatmeal	II	D
Ethohexadiol	III	D
Eucalyptol	III	D
Hydrocortisone preparations	III	D,S
Juniper tar	III	D,S
Lauryl isoquinolinium bromide	III	D
Menthol	III	D,S
Methylbenzethonium chloride	III	C
Methyl salicylate	III	D
Phenol and Phenolate sodium	III	S
Pine tar preparations	III	D,S
Povidone-iodine	III	D,S
Salicylic acid	I	D,S
Selenium sulfide	I	D
Sodium salicylate	III	D,S
Sulfur	I	D
Thymol	III	D
Undecylenate preparations	III	D,S
Zinc pyrithione	I	D,S

*Category I for shampoo use only; Category III for other uses

D = dandruff; S = seborrhea; C = cradle cap

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NORTH CAROLINA PHARMACY WEEK OCTOBER 12–18, 1986 "CAN WE TALK?"

Dear North Carolina Pharmacist,

As the summer ends and we turn our thoughts to football games, changing leaves, and cooler weather, it is time to remember one more special event that occurs each fall — **North Carolina Pharmacy Week.** Once again, the North Carolina Pharmaceutical Association (NCPhA) and the North Carolina Society of Hospital Pharmacists (NCSHP) have begun promotional activities for this event. Governor James G. Martin has proclaimed October 12–18, 1986, as **North Carolina Week** in recognition of the role of pharmacists in the health care system.

The steering committee for the 1986 **N.C. Pharmacy Week** felt that we should stress the role of the pharmacist in patient counseling and chose as our theme "Pharmacy—The Profession of Communicators." "Can We Talk?" was selected as the slogan for our promotional poster and buttons. This theme ties in nicely with two national campaigns that are currently underway: 1) NCPIE— "Give the Answers" and 2) APhA—PMA "Your Health is in Your Hands." Sample materials from both of these programs have been included in your packet.

To kick off **N.C. Pharmacy Week,** Glaxo, Inc. is providing toll free phone lines on Saturday, October 11. Pharmacists from throughout the state will be available to answer these lines and handle patient inquiries. In an attempt to improve the visibility of the phone-in, the toll-free lines will be set up in a Durham area mall. Local pharmacy association presidents have been encouraged to develop special activities on a local level and work with the media in their respective areas. Individual pharmacists should plan to use this week as an opportunity to promote their professional services to the public.

Make plans now to join pharmacists throughout the state in promoting our role as drug information experts. We hope that with your participation this year will be the best ever.

Sincerely,

N.C. Pharmacy Week Steering Committee
DeAnne Labrecque
Charlotte Mize
Lori Tutterow

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Very special thanks to the following companies, who through educational grants, participation in the Exhibit Program, or other donations, helped ensure a successful 105th Annual Convention in Greensboro.

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CARRBORO PHARMACY ROBBED

A man wielding a handgun held up Vaughan's Independent Pharmacy Thursday afternoon, June 19 and escaped with an undetermined amount of drugs. The robber told the pharmacist what he wanted and fled. There were no injuries.

FLETCHER PHARMACY ROBBED

Fletcher Revcoe Discount Pharmacy was robbed Sunday, May 25 by a lone gunman, who

cont. on p. 28

APhA BOARD UNVEILS ORGANIZATIONAL PLAN IN RESPONSE TO MEMBER DESIRES

The American Pharmaceutical Association (APhA) Board of Trustees has unveiled an organizational plan for APhA designed to meet members' current and future needs and tailored to fulfill member desires.

APhA will remain "an organization by, for and of pharmacists" as a result of opposition to the October 1985 proposal to expand membership to scientists, educators, pharmacy association and industry executives, and students not eligible for active membership. The Board has announced they will not be recommending to the membership any change in the current definition of Active membership.

The Association's membership would be divided into three Academies, each of which would conduct the major activities of APhA through Standing Committees on Education Programs, Publications, Awards and Policy. The interests of management and practice would be served by a broadened Academy of Pharmacy Practice and Management (APPM). The research and science interests of all members and the role of science in the profession would be served by a broadened Academy of Pharmaceutical Research and Science (APRS). Students would be organized into the Academy of Students of Pharmacy (ASP).

Each Academy will continue to have an Executive Committee which would be composed of a chairman, chairman-elect and two members-at-large. Sections would be strengthened by enlarged Executive Committees composed in the same manner as the Academy Executive Committees. And the Executive Committees would serve as the Academy (or Section) committee on nominations, with the right by Academy (or Section) members to petition.

The Student House of Delegates would be retained with its functions extended to include action on the reports of the four ASP Standing Committees. Each member of the three Academy Executive Committees would automatically serve as a Chairman of one of the four Academy Standing Committees. To further strengthen Sections, each member of the Section Executive Committee would automatically serve as a member of one of the Academy Standing Committees. Two members of each Academy Standing Committee would then be automatic members of the equivalent APhA Advisory Committee.

The APhA Committee on Nominations would be composed of two *ex officio* (with vote) members — the immediate past Chairman of the APhA Board of Trustees and the immediate past Speaker of the APhA House of Delegates — and three members-at-large, with no member serving more than three consecutive years. The Board agrees that the House of Delegates should establish its own process for the nomination of its presiding officer.

In response to the House of Delegates' desire to be informed on the organizational changes to be recommended to the membership by the Board of Trustees, a special session of the House will be held in Washington, D.C., from 1:00 p.m. to 3:00 p.m., Sunday, September 21, 1986.

The revised proposal of the Board is accompanied by a letter to the membership asking them to carefully study the proposal. "It will help you prepare for a vote to amend the bylaws to be sent to you later this year," the Board told the membership.

The Board added: "We listened to the comments of the membership and made substantial changes in the original proposal to assure a more democratic organization with greater opportunity for self determination at the House, the Academy and the Section levels. We also view all of these individual proposals as an integrated plan. It is a whole fabric tailored to the current and future needs of the profession and altered to fit the unique perspectives of APhA members. We enthusiastically endorse this revised plan and hope you will as well."

---

cont. from p. 27

was later identified and also charged with the murder of a Hendersonville man soon after the robbery. The alleged robber was wounded and taken to a local hospital. He had been arrested just a few days earlier in a drug roundup and was free on $10,000 bond.

DURHAM DRUG DESTROYED BY FIRE

Durham Drug Company, owned and operated by Bill and Ida Wells since 1953, was totally destroyed by a fire Saturday night, June 28. The fire was believed to have been started by lightning. Durham Drug had been in business for 75 years. BC Headache Powders were formulated in the store.

CORRESPONDENCE COURSE QUIZ

Dandruff/Seborrhea

1. Which of the following definitions best describes the term "squamae"?
   a. compacted, dead, dry cells
   b. the lower level of cells lying directly on top of the dermis
   c. pigment producing cells in the subcutaneous areas
   d. the scaling of large clumps of epithelial cells
2. The usual time that it takes for dead epithelial cells to slough off and be replaced by new cells from underneath is:
   a. 14 hours
   b. 14 days
   c. 14 weeks
   d. 14 months
3. Selenium sulfide exerts its antidandruff activity by:
   a. depressing epithelial cell division.
   b. lowering the surface tension of the cell wall of susceptible microorganisms.
   c. dissolving the cement substance that holds cells together.
   d. inhibiting the sensation of pain and itching.
4. Cradle cap is a form of:
   a. dandruff.
   b. seborrhea.
5. Which of the following definitions best describes the term "keratin"?
   a. compacted, dead, dry cells
   b. the lower level of cells lying directly on top of the dermis
   c. pigment producing cells in the subcutaneous areas
   d. the scaling of large clumps of epithelial cells
6. The FDA Panel that reviewed OTC topical products found that all of the following are safe and effective in shampoo dosage form for self-medicating both dandruff and seborrhea WITH THE EXCEPTION OF:
   a. borate preparations.
   b. coal tar preparations.
   c. salicylic acid preparations.
   d. zinc pyrithione preparations.
7. Which of the following symptoms is common to both dandruff and seborrhea?
   a. excessive epidermal cell shedding rate
   b. inflammation of surrounding tissue
   c. constant, severe itching
   d. decreased sebum production
8. The concentration of which of the following microorganisms is DEPRESSED in the areas of skin affected by seborrhea?
   a. *Candida albicans*
   b. *Pityrosporum ovale*
   c. *Propionibacterium acnes*
   d. *Staphylococcus aureus*
9. Which of the following definitions best describes the term "basal epithelial cells"?
   a. compacted, dead, dry cells
   b. the lower level of cells lying directly on top of the dermis
   c. pigment producing cells in the subcutaneous areas
   d. the scaling of large clumps of epithelial cells
10. Keratolytics exert antidandruff activity by:
    a. depressing epithelial cell division.
    b. lowering the surface tension of the cell wall of susceptible microorganisms.
    c. dissolving the cement substance that holds cells together.
    d. inhibiting the sensation of pain and itching.
11. All of the following are available OTC in the strengths listed EXCEPT:
    a. Salicylic acid 2–3%
    b. Selenium sulfide 2–4%
    c. Sulfur 2–5%
    d. Zinc pyrithione 1–2%
12. Which of the following statements is true?
    a. The epidermis has a rich supply of blood running through it.
    b. Seborrheic conditions of the eyelids are effectively treated with OTC antimicrobial products.
    c. Shampoos containing coal tar derivatives are considered to be safe and effective for self-treatment of dandruff.
    d. Dandruff conditions are most prevalent in persons under the age of 50.
13. Dandruff is most likely caused by which of the following:
    a. Improper hygiene
    b. A deficiency of vitamin B
    c. Incomplete keratinization
    d. Hormonal imbalance

continued on page 30

Correspondence Quiz

continued from page 29

14. The intensity of flaking in dandruff is greatest during:
    a. January to March.
    b. April to June.
    c. July to September.
    d. October to December.

15. All of the following statements about seborrhea are true EXCEPT:
    a. epithelial cell turnover is greater with seborrhea than dandruff.
    b. seborrhea can occur on any hairy or skinfold area of the body but is most common on the scalp.
    c. unlike dandruff, itching is a common symptom of seborrhea.
    d. it has been shown that all persons with seborrhea have an increased sebum production.

It has come to our attention that Paid Prescriptions has launched a nationwide "audit" of prescriptions filled by pharmacies participating in third party programs processed through the Paid system. *The "audit" consists of letters sent to patients requesting that they wrap up a sample of certain oral medications and mail that sample back to Paid.*

Already reports have it that the California Board of Pharmacy has refused to allow Paid to conduct this action in the state. It has been suggested that it may be illegal for Paid to receive legend drugs in this manner, since they are not licensed to possess legend drugs without a prescription. In addition, the action by Paid, which promises to have potentially dangerous prescription drugs circulating through the U.S. mails, represents a potential public health threat.

The intent of this memorandum is to alert you to this action by Paid, and to ask that you contact NCPhA with additional information you may obtain on the issue.

Cut Out or Reproduce and Mail

CONTINUING PHARMACEUTICAL EDUCATION
Dandruff/Seborrhea

- Attach Mailing label from **The Carolina Journal of Pharmacy** in space provided (or print name and address) and mail completed questionnaire to: NCPhA, P.O. Box 151, Chapel Hill, NC 27514.
- You may submit completed questionnaires on a monthly, quarterly, or less frequent basis depending on which procedure is most advantageous for you in your pharmacy practice.
- NCPhA will maintain a record of your completed CE credit hours. Upon successful completion of each program you shall receive a certificate for one hour of Board approved CE.
- If the answers to more than two questions are incorrect, the questionnaire will not be acceptable for CE credit. If your questionnaire is not accepted you will be notified within 10 days and given an opportunity to submit a second questionnaire.

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3. a b c d	*6. a b c d*	*9. a b c d*	*12. a b c d*	*15. a b c d*

Evaluation ☐ Excellent ☐ Good ☐ Fair ☐ Poor

How long did it take you to read the article and complete the exam? _____

UNC SCHOOL OF PHARMACY NEWS ITEMS

UNC Pharmacy students were awarded three of the twelve Undergraduate Research Awards made by the Society of Sigma Xi, the scientific research society. The students are Laurie O'Daniel of New Bern, Stephanie Perry of Fayetteville, and Janeen Vanhooke of Hillsborough.

Dean Tom S. Miya is serving as a U.S. co-chair for a Symposium H-1, Environmental Toxicology. The Symposium is one of several being planned jointly by the American Pharmaceutical Association Academy of Pharmaceutical Sciences and the Japan Pharmaceutical Society. The meeting is planned for Honolulu during December 1987.

The UNC School of Pharmacy hosted the 20th American Chemical Society Division of Medicinal Chemistry Symposium. Associate Dean George Cocolas was local program chairman. The symposium, held June 15–19, attended by almost 500 scientists from the U.S. and abroad, was highlighted by an after-dinner presentation by 1979 Nobel Laureate Herbert C. Brown. Many positive comments were received from the attendees on the quality of the scientific program and the overall planning of the Symposium.

Dr. Phillip Bowen will join the Medicinal Chemistry and Natural Products faculty this fall. He earned his Ph.D. in organic chemistry from Emory University and is completing two years of postdoctoral studies at the University of Georgia. His theoretical oganic, synthesis and molecular modeling skills will add a new dimension to teaching and research.

Dr. Kim Brouwer has joined the Pharmaceutics faculty. She holds the B.S. in Pharmacy and Doctor of Pharmacy degrees and earned her Ph.D. in Pharmaceutics at the University of Kentucky. She completed two years of postdoctoral training in pharmacology/toxicology, also at Kentucky.

IMPAIRED PHARMACIST STUDY SUBJECTS SOUGHT

Pharmacists who have recovered from alcoholism and/or addiction to other drugs are needed for a face-to-face interview through which they can share their experiences in order to help their colleagues who may still be in trouble.

The interviews will be conducted as a part of a study of impaired pharmacists to be conducted by LeClair Bissell, author of the landmark book, *Alcoholism in the Professions.*

The study is not designed to gather prevalence data, but it will gather information about the behavior of colleagues, regulatory boards, and others which either helped or hindered the recovery process. It will also permit comparison of pharmacists with other health care professionals in their choice of drugs, attempts to get help, sanctions imposed, interventions, and many other concerns. The study will provide useful data on which to base the planning for earlier and more effective case finding and referral into treatment.

Pharmacist subjects must be entirely clean/dry for a minimum of one year at the time of actual interview. "All interviewers are mature people who share a similar life experience and who do not gossip," Dr. Bissell assures, "and confidentiality and anonymity traditions are strictly respected." APhA, although actively involved in providing technical and research design assistance, will not collect raw data or have access to information that might identify any individual.

Recovering pharmacists willing to participate — or who know colleagues who are willing to take part — should contact the chief investigator directly: LeClair Bissell, M.D., 130 West 16th Street, New York, NY 10011. A brief note will suffice, giving name, address and telephone number. Also include information about when contact would be most convenient and whether or not you can talk freely if telephoned.

MALPRACTICE INSURANCE

Having trouble with your professional liability insurance? Has your plan through a national organization been canceled? Don't despair. Through your membership in the North Carolina Pharmaceutical Association, you can buy malpractice insurance at the most reasonable cost anywhere, with St. Paul Fire and Marine Insurance Company, St. Paul, MN. For more information or for an application, call the Association office.

A HOT WEATHER WARNING FOR OLDER PEOPLE

Although summer is traditionally a time for outdoor recreation, the National Institute on Aging warns that hot, humid weather may pose severe health problems for a great many people. Older people, particularly, should take necessary steps to lessen the risks of heat-related illnesses.

Heat stress, or hyperthermia, can take several different forms from the potentially fatal heat stroke to a less serious heat fatigue. The two most common forms of heat stress are heat stroke and heat exhaustion. Of the two, heat stroke is especially dangerous and requires immediate medical attention.

Regardless of outside temperatures, the healthy human body maintains a temperature in a range close to 98.6 degrees Fahrenheit (37 degrees Celsius). In hot weather or during vigorous activity, the body perspires. As the perspiration evaporates from the skin, the body is cooled, maintaining its normal temperature. If challenged by long periods of oppressive heat, the body may lose its ability to cool itself. Even when the weather is not extremely hot, older people may be more subject to heat-related conditions because of certain health and environmental factors.

Medical factors which may make a person prone to heat-related illnesses include heart, lung, and kidney diseases, as well as any condition which causes weakness or fever. Diseases such as diabetes, which require special diets, may also place a person at higher risk. The effects of heat on an existing health condition should be discussed with a doctor.

People taking diuretics, sedatives and tranquilizers, anticholinergic drugs, and some heart and blood pressure medications which alter the ability to sweat should be aware of the increased risk of hyperthermia. It is important, however, that people taking these medications continue to do so and discuss possible problems with a doctor. Other factors which may make a person more susceptible to heat-related illnesses are changes in the skin, slowed circulation, and inefficient sweat glands caused by the normal aging process, obesity or alcoholism.

Certain environmental factors also affect the body's ability to regulate its temperature. Poor ventilation, improper clothing, and the lack of fluids contribute to a person's inability to stay cool in the heat.

Heat stress can be experienced in different degrees. Heat fatigue is a feeling of weakness brought on by exposure to extreme heat. Symptoms include cool, moist skin and a weakened pulse. The person may feel faint. Heat syncope is a sudden dizziness often experienced after exercising in the heat by people who are unaccustomed to hot weather. The person may actually faint. The skin is moist and cool, the pulse may be weakened, and the heart rate rapid. Heat cramps are muscle spasms in the abdomen, arms or legs, often felt after strenuous activity. They are usually caused by salt depletion, although people are advised against taking salt tablets without first asking a doctor. The skin is usually moist and cool and the pulse is normal or slightly elevated. Body temperature usually remains normal in these conditions.

Heat exhaustion is a more serious warning that the body is getting too hot. It is probably the most common form of heat-related stress caused by the body's loss of water and salt. A person may exhibit thirst, giddiness, weakness, profuse sweating, loss of coordination, lightheadedness, loss of appetite, and nausea. Body temperature is often elevated, but usually not higher than 101 degrees. The pulse rate is normal or raised. The victim is probably sweaty and pale but the skin is cold and clammy. Heat exhaustion may be treated in several ways. The victim should lie down in a cool place, preferably one that is air-conditioned, and be given fluids. Avoid alcohol and caffeine. Water and fruit and vegetable juices are best. Encourage the individual to shower, bathe, or sponge off with cool water. If left untreated, heat exhaustion can progress to heat stroke.

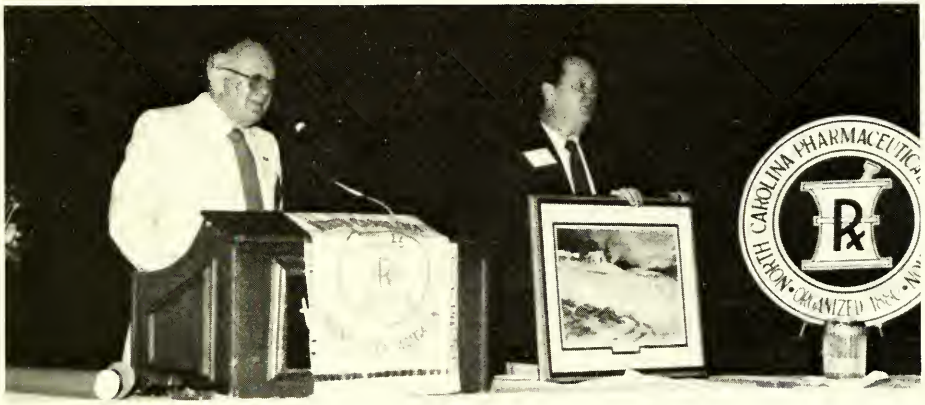
Heat stroke can be LIFE-THREATENING! Immediate medical attention is required. The death rate for unattended heat stroke approaches 100 percent. If someone you know exhibits signs of heat stroke, emergency medical assistance is essential. The condition is usually preceded by headache, dizziness, nausea, confusion and even convulsions. The victim may be flushed but may not be perspiring. The pulse is generally strong and rapid. The body temperature, taken rectally, is 104 degrees Fahrenheit (40 degrees Celsius) or higher, and rising. The person may lose consciousness.

It is easy to avoid heat-related illnesses by simply following some basic, common sense procedures:

— Drink plenty of water and juices.
— Bathe or shower frequently using cool water.
— Wear light-weight, light-colored, loose fitting

clothing; cotton is best.
— Avoid vigorous outdoor activity during the hottest part of the day (noon to 4 p.m.). Wear a hat or use an umbrella when out in the sun.
— Use fans and air conditioners liberally. If no air conditioner is available, keep shades or curtains down during daytime hours and windows open at night.
— Visit air-conditioned places such as shopping malls, libraries and theatres but avoid overcrowded areas. Many communities now provide an older person with transportation when none other is available.
— Avoid heavy meals. Limit the use of ovens.
— Stay in an air-conditioned place on especially hot and humid days, particularly when there is an air pollution alert in effect.

Above all, the hot days of summer should be respected. Heat-related illnesses can become serious if proper precautions are not taken. It is important to realize that older people are at particular risk of hyperthermia. Many people die of heat stroke each year; the majority are over 50 years old. With good, sound judgment and knowledge of preventive measures, the summer can remain a time of fun and leisure for everyone.



NCPhA President Keith Fearing presides at the 1986 Convention while Al Mebane exhibits the watercolor "I Hope The Pipes Don't Freeze Tonight", donated by Joe Miller to the NCPhA.

NATIONAL LEGISLATIVE ACTION

House Bill H.R.4820, "the Prescription Drug Marketing Act of 1986", introduced as a result of hearings of the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee, needs your support.

The bill would ban reimportation of pharmaceuticals produced in this country and shipped abroad. The only exception would be those returned to the original manufacturer. The bill would make it a felony to sell or exchange (1) Pharmaceutical samples, (2) Pharmaceuticals sold for export only, (3) Pharmaceuticals purchased by hospitals, clinics, or other health agencies for the exclusive use of those institutions and not intended for resale, and (4) pharmaceuticals dontated or supplied at reduced prices to charitable institutions in the United States or abroad for their institutional use. The bill would also prohibit the dispensing of samples by pharmaceutical company sales representatives and prohibit the practice of providing physical samples to prescribers. There are several other important provisions of this bill which will be mailed in the *Tar Heel Digest,* the monthly newsletter of the NCPhA.

If you agree with this legislation, contact your congressman now, by letter or phone or when he is at home and express your position. The NCPhA office has written each congressman but a letter from home is more important than a letter from an association. Your comments will count. Mail correspondence to The Honorable _____, US House of Representatives, Washington DC 20515.

APhA/PMA PUBLIC SERVICE CAMPAIGN AIMED AT NON-COMPLIANT PATIENT

The nation's pharmacists and pharmaceutical manufacturers are joining forces to conduct a public education campaign aimed at Americans who take their medicines improperly.

The American Pharmaceutical Association (APhA) and the Pharmaceutical Manufacturers Association (PMA) announced they are co-sponsoring a campaign aimed at the one third to one half of all patients who take their medicine at the wrong times, in the wrong amounts, stop taking it too soon, and sometimes fail to take it at all. The theme of the campaign is "Your Health Is In Your Hands."

The failure to follow medication instructions and its consequences is a growing public health problem, according to both APhA and PMA. They cited studies indicating that 125,000 die each year as a result of failure to take medication as prescribed, hundreds of thousands are hospitalized and millions of workdays are lost.

APhA President John F. Schlegel and PMA President Gerald J. Mossinghoff stated television and radio messages are being mailed to 659 TV stations and 1,000 radio stations around the country urging Americans to "do what your doctor and pharmacist say."

One television/radio message features excuses frequently used by non-compliers:

"I don't have time today."

"I forget how much to take."

"I don't like the way it makes me feel."

"I'm feeling better so I stopped taking it."

Another message notes that modern medicines are better and easier to take, but can fail to have the intended results if taken improperly.

The campaign also will feature a 5-minute film for use by members of both associations as a curtain-raiser for talks to community groups. Other campaign materials will include posters and prescription package inserts for use by pharmacists throughout the country.

The joint campaign by the two associations is a "historic first," Mossinghoff said, calling it a "logical alliance to better educate consumers about our products." Schlegel said, "With the anticipated support of the state pharmaceutical associations, this program will do much to reinforce the value of pharmaceutical services as prescribed by the public."

COOPERATION KEY ELEMENT IN COLLECTIONS

"I had a letter this morning from a creditor who had gone to different assistance programs to get some sort of help for a debtor," said Donna Moser, Service Representative at I. C. System. "He had taken his own time to do this." But no help was available. "So he asked us to just get small token payments from this person," Donna said.

This is an example of the cooperation from creditors which I. C. System Service Representatives have found to be invaluable in the recovery of past due accounts.

Of course, to cooperate does not mean you have to go the same route this creditor did. You also don't need to necessarily take every word a debtor hands you as absolute fact. Part of I. C. System's job is to judge the merit of debtor arguments while uncovering the real problem that has been holding up a payment.

"Sometimes a debtor will write and say that he's lost his job and he doesn't think his creditor is aware of this," said Judy Benkufsky. "He tells us he's happy with the product or the service and he wants to continue going there, but he's embarrassed by the financial situation."

Dave Work seems pleased that Jack Watts was selected 1986 Pharmacist-of-the-Year. The announcement was made during the annual convention in Greensboro.

DEATHS

LOAN FUND ESTABLISHED FOR PHARMACIST KILLED IN ACCIDENT

Pharmacists and friends of Stephen B. Gentry, Pfafftown, have established a loan fund in his memory in the Consolidated Student Loan Fund of the North Carolina Pharmaceutical Association. Contributions in excess of one thousand dollars have been received from colleagues and from Crown Drugs, with whom Gentry was associated in Stanleyville.

He was killed in an automobile accident Friday night, June 20, and was 25 years old. He was a 1983 graduate of the University of North Carolina School of Pharmacy, and is survived by his wife Jan. Contributions to the Stephen B. Gentry Memorial Loan Fund may be sent to the NCPhA Central Office in Chapel Hill.

THOMAS B. WAUGH

Tom Waugh, Climax, died at home July 9, 1986. He was a retired salesman with Justice Drug Company, with whom he worked for forty-seven years. He retired in 1966. Waugh was a life member of the Traveling Members Auxiliary.

JOHN THOMAS STEVENSON

John T. Stevenson, Elizabeth City, died July 6, 1986, at Albemarle Hospital. He was 88 years old. Mr. Stevenson was a native of Elizabeth City and a graduate of the University of North Carolina School of Pharmacy. He and Harold Overman founded "Overman-Stevenson Pharmacy" in 1925 and he worked there until his retirement in 1982.

He served as President of the North Carolina Pharmaceutical Association in 1962–63, having joined the association in 1919. He was a member of the American Pharmaceutical Association, the National Association of Retail Druggists and was a past president of the Northeastern Carolina Pharmaceutical Society. He was selected as 1968 Pharmacist of the Year by the North Carolina Pharmaceutical Association and was honored at a dinner in Elizabeth City. He was a past vestryman in Christ Episcopal Church, a fifty year member of the Rotary Club, a Mason and a member of the Elks Club. He served on the Elizabeth City City Council and Chamber of Commerce, the Pasquotank Arts Council and was a member of the North Carolina Museum of Arts.

BIRTHS

KATHY D'ACHILLE and Ron McCracken, Clemmons, announce the birth of their son Delaney Jay (Lane) on July 20, 1986. He weighed 7 lbs 12 oz. and was 21 inches long.

MARRIAGES

KIMBERLY DAWN STARLING of Pine Level and Richard Walter Krentz, Jr. of Goldsboro were married Saturday May 17, 1986 at St. Paul United Methodist Church, Goldsboro.

The bride, a graduate of the University of North Carolina at Chapel Hill School of Pharmacy, is a pharmacist at N.C. Baptist Hospital. The bridegroom, a graduate of East Carolina University, is a credit manager at Wachovia. They live in Winston-Salem.

* * *

MARTHA JO HARRELSON of Whiteville and Arthur Gilbert Stanley of Jacksonville were married Saturday, July 12, in a 4 p.m. double-ring ceremony at the Whiteville First Baptist Church.

The bride has a B.S. degree in pharmacy from the University of North Carolina at Chapel Hill School of Pharmacy and is employed with Kerr Drug Stores. The groom is a graduate of Appalachian State University with a B.S. degree in accounting and is employed with the U.S. Marine Corps, Internal Audit Office. The couple reside in Jacksonville.

* * *

Mary Shannon Benton and HUGH DAN HARDY, JR., both of Raleigh, were united in marriage at 2 p.m. May 17, 1986 in St. Michael's Episcopal Church, Raleigh. The Rev. Larry Brown of Raleigh and the Rev. Joseph Dunlap of Knightdale officiated at the double-ring ceremony.

The bride, a graduate of Cary High School, is employed by the N.C. Department of Justice. The bridegroom is a graduate of the University of North Carolina at Chapel Hill School of Pharmacy and is employed as a pharmacist by Kerr Drug Stores. The couple live in Raleigh.

CLASSIFIED ADVERTISING

Classified advertising (single issue insertion) 25 cents a word with a minimum charge of $5.00 per insertion. Payment to acompany order.

Names and addresses will be published unless a box number is requested.

In replying to "blind" ads, address Ad. No., Carolina Journal of Pharmacy, P.O. Box 151, Chapel Hill, NC 27514. Telephone (919) 967-2237.

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COMPUTER FOR SALE: New Radio Shack TRS 80 Model 4 Computer with DMP-120 Printer with two disk drives and pharmacy software that includes "Radio Shack Accounts Payable" program and "Profile 4 Plus." To settle estate. (Bought for a new pharmacy) $1500.00. Call 919-383-1798.

ASSISTANT DIRECTOR OF PHARMACY: interviews are now being held with qualified professionals for this position. Successful candidate will report directly to the Director of Pharmacy. Licensure to practice as registered pharmacist in North Carolina required. We offer an excellent compensation and benefit package. Interested and qualified professionals may contact: Highsmith-Rainey Memorial Hospital, Personnel Office, 150 Robeson St., Fayetteville NC 28301. (919) 483-7400 ext. 161. Affiliate of HCA. EOE M/F/H

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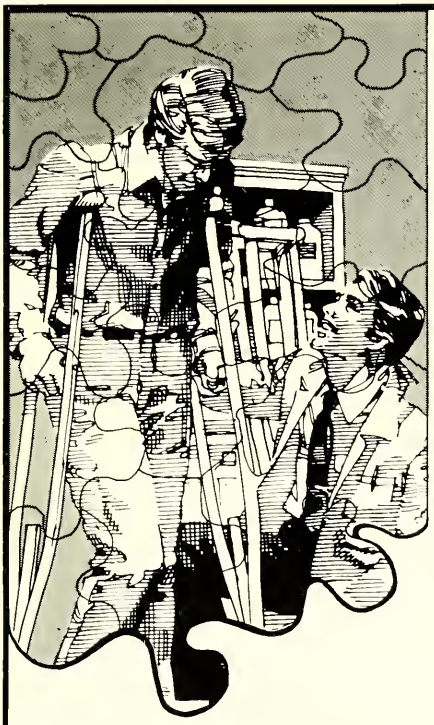

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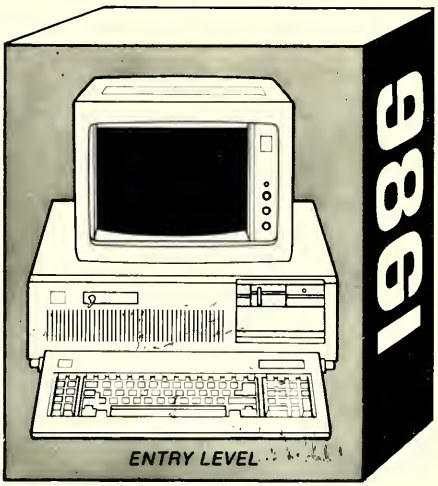

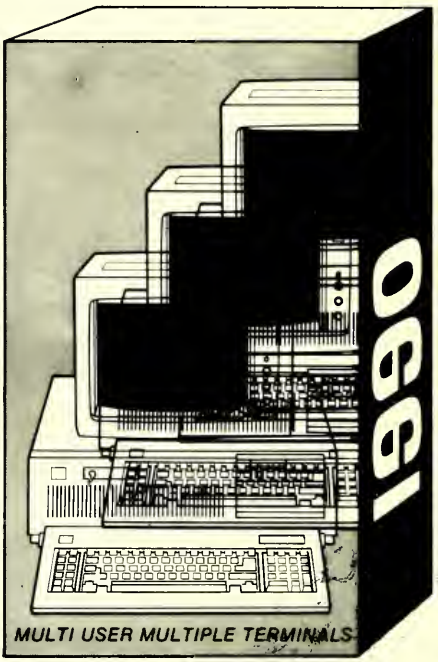

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AUGUST 1986 VOLUME 66 NUMBER 8

Photo by Colorcraft

Left to right: Bob Smith, UNC School of Pharmacy, presents the Syntex Practioner-Instructor of the Year Award jointly to Bill Van Valkenburg and J.C. McGee, Asheville, while Jim Perrow, Syntex representative, looks on. Photo by Colorcraft

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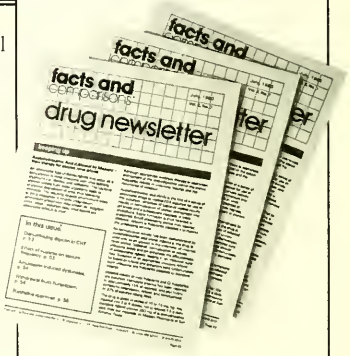

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THEN AND NOW
(NCPhA Presidential Addresses Given One Year Apart)

W. Artemus West
1984–85 President
Raleigh, April 12, 1985

W. A. West

President-Elect Brown, Convention Guest, Members, and Ladies and Gentlemen:

I recently spent a short time observing Pharmacy in London, England and feel it appropriate to borrow from Dickens in relating to you a report of the year just past.

"It was the age of foolishness, it was the epoch of belief, it was the epoch of incredulity, it was the season of light, it was the season of darkness, it was the spring of hope, it was the winter of despair, we had everything before us, we had nothing before us, we were going direct to Heaven, we were all going direct the other way — in short, the period was so far like the present period, that some of its noisiest authorities insisted on its being received, for good or for evil, in the superlative degree of comparison only."

Believe me there is some bad news relating to our profession but thank goodness there is also good news.

The bylaws of our organization state that your president shall present a report on the affairs of the association at each annual meeting. I shall do so in as concise and brief manner as possible.

On the national scene this was a year of change and new leadership in several of the national pharmacy organizations. I was privileged to attend the APhA convention in Montreal last May and met John Schlegal, the new president of APhA. North Carolina is a state that has practitioners active in all the national associations, therefore many are well aware of things happening on the national scene which affect pharmacy here in North Carolina. There seems to be a mood of conciliatory cooperation between the major groups and hopefully this will hold true on the national level so that our profession can present a united front on things that affect us all in our practices. It was also a privilege to visit with Charles West in Washington and discuss NARD's Legislative Conference and the many problems confronting pharmacy. Mr. West has since assumed leadership of NARD and we are delighted that he is a part of our convention this year. While in Washington, Jesse Pike and I visited both North Carolina Senators Helms and East, as well as several NC Congressmen. As NARD has been saying for several years we need to either get active in politics or get out of pharmacy. This is especially true if we hope to participate in our profession as free entrepreneurial business and professional people. I would encourage our members to continue to support by membership the national organization which best represents you. On the state level I encourage you to be a member of Pharmpac.

Politically on the state level your association through the legislative committee has been active. In January the legislative committee developed a package of recommended legislative goals which included: (1) Increase the medicaid fee to $3.50, (2) Unit dose package reimbursement, (3) Opposition to including pharmacy in the Administrative Procedures Act, (4) Opposition to the modifications in the Pharmacy Practice Act to accomodate health departments dispensing, and (5) Legislation to mandate inclusion of a pharmacist on each AHEC regional governing board. We also have hired a lobbyist for the association while the legislature is in session. Mrs. Mary Jarrell of High Point is serving in this capacity. She will keep a finger on the pulse of the legislature, as Ed Nye our former lobbyist did. Mr. Nye is now your president's

legislative representative and has assured me of his continued interest and help on the part of pharmacy. It has always seemed to me that pharmacists themselves are the best lobbyists, and I call on the membership to be ready if and when the call goes out from the association to support or speak against any legislation that may effect us. We can alert you through the Chapel Hill office. You can affect legislation by knowing and speaking to your legislator. I urge you to be active when called upon.

This year your association has endorsed insurance plans that we feel will be beneficial to the members. There is now available insurance relating to business property, casualty insurance and also professional liability. Likewise a policy is available relating to income replacement.

I have asked the Impaired Pharmacist task force formed by Dave Claytor, to continue, and I encourage this group to come up with specific guidelines and procedures. I have appointed Dave Claytor, Keith Elmore, and incoming president Shelton Brown to meet with the task force and representatives of NCSHP to continue their efforts. It might be noted that the disability insurance being offered to our members would give income to anyone needing treatment and the insurance company would participate in an approved rehabilitation program. Our group hospitalization through Pilot Life has available $500,000.00 for hospital treatment.

This past summer your association was host to all the Southeastern Pharmaceutical Executives. I wish each member could have heard the expressions of state executives from Kentucky and Maryland all the way down to Florida and Louisiana. They were most complimentary of our state associations efficient staff and headquarters building. I wish to express my own appreciation to Al, Betsy, Debbie and Erie for the efficient and dedicated work that is done on a day to day basis at the Institute of Pharmacy. Working closely with the office allows one to see the tremendous amount of work that goes through this office in a years time. While paying tribute I'd like to give a special thanks to the committees that have served you, some at considerable personal sacrifice of time and money to attend their respective meetings. I have tried to attend as many as possible, but didn't get to all. Thank you for serving and advancing your profession with your input.

Pharmacy Week in North Carolina was successful. I'd like to thank all who worked so hard to get all this material and publicity together, and thank also the members who participated to make it a success.

Mandatory continuing education arrived this year, and though I personally have always had misgivings about being forced to improve yourself professionally, I must admit that this regulation seems to have at least brought us into a position of more pharmacists getting together for seminars. To assure that this regulation need not be a burden on anyone, your association has been publishing C.E. correspondence courses in the Journal and also with the Pharmacy School are sponsoring C.E. seminars that should make it easy for all of us to obtain the required hours. I would encourage all to not just seek continuing education but that we individually set goals of continuing competence for ourselves.

I'm happy to report that during this year the different interests of our association; independents, chain, and hospital have worked together to advance common goals that would be beneficial to all of the profession. I've been privileged to sit in on NCSHP meetings and in turn the President and Executive Director of NCSHP have met with the Executive Committee of the association. In February, the Board of Pharmacy hosted a meeting with most all disciplines of the profession in attendance; the School, the Board, NCSHP, NCPhA, and representatives from three chains. I would suggest such a weekend forum be continued if possible next year and that representatives from pharmaceutical manufacturers be asked to participate. This was an excellent give and take from the many interests in pharmacy in our state. Only good can come from communicating with our colleagues.

A few weeks ago the Executive Director and I met with the president and other high officials of Pilot Life Insurance Company. Pilot Life is the company with whom many of our members have their group hospitalization. The subject of our meeting was a proposal to Pilot Life by a national drug chain corporation, in the guise of cost-containment, to give Pilot major medical enrollees a 10% discount on prescriptions and other front merchandise. Pilot is reluctant to sign anything without bringing it to our attention and trying to see if there is any way members of NCPhA could or would be involved in such a program. I have invited Pilot Life to meet with

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President's Address
Continued from page 6

the Executive Committee at the earliest opportunity to present their views. From my perspective, it is another example of using discounts as a marketing tool and really would have no appreciable affect on actual cost of medication to the consuming public. It is my opinion that our professional image has been hurt more by the "discount" game than any other thing of recent years.

Third party programs continue to be a problem with no apparent handle to grasp hold of. Just this past week we met with Louis M. Sesti, Executive Director of Michigan Pharmaceutical Association. Mr. Sesti presented an interesting possibility for pharmacists through the organization of a third party corporation separate of the NCPhA, but with pharmacists interests in mind, to present their own third party programs to compete with other companies. Your Association will pursue this and make some decisions in the near future as to whether we will join with other state associations in this approach. Hopefully this may be one way to compete with the HMO, PPO and mail order challenges that seem to lie ahead.

Change has been rapid in our practices, but this year change has also come to pharmaceutical education within the state. Several pharmacists were invited to Buies Creek a few weeks back to be informed of the plans of Campbell University to begin a School of Pharmacy. Dr. Wiggins assures us that Campbell is well funded and is making plans to begin a quality pharmacy education program at his school. The Association stands ready to work with any accredited pharmacy school and we hope that such cooperation will result in improvement in the profession.

As your president I have tried to soften my prejudices for independent retail community pharmacy. I know there is a revolution in health-care, but I must speak my mind on some trends

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that I feel are shaping the future of pharmacy and not all are good. Sadly, the majority of graduating students will not even consider store ownership and those who do may not have the business knowledge or financial backing to do so. What better place to change this attitude than in the pharmacy schools. So much effort is devoted to clinical knowledge and so little to business that there exists a wide breach between these two philosophies. You don't need to be in a clinical setting to be a professional. Professionalism is merely satisfying customers needs.

Retail Pharmacy has existed much longer than any other aspect of our profession and the demise of the individual desire of the pharmacy professional to be his or her own entrepreneurial self-employed boss will be in my opinion a great detriment to our professions growth and expanded roll in the future.

The presidency of the NCPhA is an elective office. You honored my father thirty years ago with this position. He loved pharmacy and his colleagues and friends in the NCPhA. I thank you for allowing me to serve in the same position. Thank you.

Date: September 15, 1986

To: All Municipalities

From: Herman M. Satterwhite
Service Administrator

Subject: PCS Dispensing Fee

The purpose of this memo is to inform you that the Board of Trustees for the Municipal Insurance Trust (MIT) of North Carolina at their last meeting increased the PCS dispensing fee paid to pharmacies from $3.50 to $3.67 per prescription. This action comes as a result of the State of North Carolina increasing the Medicaid dispensing fee to $3.67 effective July 1, 1986.

Because of problems created by pharmacies in the past, the Board of Trustees felt that it was in MIT's best interest to keep our PCS dispensing fee equal to the State Medicaid dispensing fee.

Please notify your employees and/or pharmacies regarding this change. If you have questions or need additional information, please contact me.

President's Address
Greensboro, April 21, 1986

H. Shelton Brown, Jr.
1985-86 President

It's been a memorable year. I recently read that any task undertaken that leaves a lasting memory was worth undertaking. It *was* that type of a year. In the interest of time, I will *not* read off the twenty pages of memories collected over this past year.

The North Carolina Pharmaceutical Association is a collage of individuals with very different interests and ideas with respect to the practice of pharmacy. It is the intent and purpose of the Association to gain some order to these interests and ideas so that our profession continues to advance in the service of the health needs of our public. We all know of recent Gallup polls reflecting that our public rates us high, at this moment in time, in our practice. But, more importantly, we must advance our profession in service and continually gain the respect of those we serve. Your Association is dedicated to help you attain this lofty goal.

Powerful vectors pull against us in pharmacy today, usually by individuals outside our profession who want to change the way we

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President's Address

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practice. They charge at us from multiple fronts. Their banners identify them as Cost Containment HMO's with exclusive pharmacy contracts, Physicians dispensing, and Mail order pharmacies. They all pretend to know a better way to delivery pharmacy services to that very public that holds us in high regard. But the greatest enemy we face in this assault is APATHY!

Apathy would cause us to wait for our national organizations to overcome these challenges to our practice. Apathy would cause us to expect our Association to find the solutions. In other words, apathy would deny your Association the combined power of *your* interest and concern in preserving our profession in the manner you would want to practice in the future. If you don't take part in facing these challenges that future can be bleak.

Isn't mandatory Continuing Education wonderful. Today, more pharmacists belong to our Association. More pharmacists attend our seminars. The argument can be raised that the 1986 North Carolina pharmacist is more informed than ever before. Does this prevent loss of business to mail order houses? Does this assure you won't lose business to non-profit pharmacies that can offer medications at a fraction of your cost yet make twice your profit? Will the high level of service you offer your public insulate you from these new competitive vectors? Probably not, I submit.

Your Association has noticed these trends. Listen carefully as the committee reports are presented at our business sessions. *North Carolina pharmacists are fighting back!* As I traveled this state over the past year I heard not one person willing to yield to these onslaughts we face today. Indeed, I heard a unity of purpose and desire, from chain, independent, and institutional pharmacists alike, to rise up and meet these challenges. The time for action is now.

In a few weeks, committee preference questionnaires will be mailed to all members of NCPhA. I challenge *all* of you to get involved in *our* future. Too few have been willing to actively participate in the past, we have been carried by a very small minority of our membership. Some of us who have been active in the past, are now leaving the business of our Association to others. We all need to join in this effort.

Please allow me to step down from the soap box now. I mentioned before that it has been a remarkable year, and a memorable one. Many thanks to the Women's Auxiliary for the wonderful job they did in redecorating the Institute lobby. If you haven't visited the Institute lately, you're in for a very pleasant surprise. They were very active in this "Year of the Child", and must have collected tons of food for famine relief.

Later this morning you will hear of the Carolina Pharmacy Network from Mickey Watts and Julian Upchurch. They won't tell you the hundreds of hours, and thousands of miles they have expended developing this PPO to help you meet our challenges. We all owe them our gratitude.

A personal thanks go to Al Mebane and the Association staff — Betsy, Erie and Laura. My long distance Presidency had to challenge them more than usual. Contrary to what you've heard previously at this convention, Al probably had to oversee more committee meetings than usual when I had other commitments. I could not have served without his aid, and it was always there when I needed it. Finally, I thank the Association members who allowed me to serve, it was a remarkable year.

Editor's note. Because of printing difficulties in 1985, President West's address was not published as part of the Convention report. This joint publication will point out the different issue and emphasis each NCPhA president faces.

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Continued on page 11

We enjoyed the pleasure of their company, these four outstanding young people with their fresh faces and new ideas.

They joined The Upjohn Company as part of our 10 week National Pharmaceutical Council–Student American Pharmaceutical Association (NPC-Student APhA) Internship Program–and we got to know each other well.

We taught them about manufacturing, quality control, pharmaceutical research, marketing and sales.

They taught us that the future is in good hands. We even learned from their questions. Certainly, we took their suggestions to heart.

On graduation day we were all a little glad, a little sad and a lot wiser.

Upjohn

We will always treasure them as friends.

Front left to right:
Paula A. Eugenio–Massachusetts College of Pharmacy
Douglas J. Zurawski–University of Michigan
Dennis R. Kinder–Washington State University
Jacqueline A. Gingras–University of Wisconsin-Madison

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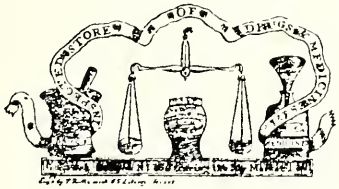

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TWENTY YEARS OF PHARMACY EDUCATION IN NORTH CAROLINA

by A.W. Pittman, Director of Academic Program Development
School of Pharmacy
University of North Carolina
Chapel Hill

Twenty-one years ago the School of Pharmacy graduated fifty-one students bestowing the degree Baccalaureate of Science in Pharmacy. Those graduates are distinguished by the fact they were the first in North Carolina to complete five years of instruction in order to qualify for licensure. At that time and for twelve years to follow, students completed one year of general education before acceptance into Pharmacy. The 1–4 program was replaced by a 2–3 configuration in 1978, but pharmacy education continued to be five years in length. In 1981 five students entered the first class that would receive the degree, Doctor of Pharmacy. Those students and ones who have followed completed six or seven years of professional education, that length dependent upon whether entry into the Program was prior to or after graduation from the baccalaureate program. Then, as it does now, the School of Pharmacy of the University of North Carolina at Chapel Hill (UNC-CH) administers two levels of professional education both of which lead students to become pharmacists.

Over those twenty years much has changed in the curriculum which prepares young men and women to become pharmacists. Those curricular changes are reviewed below in order to explain: 1) where we have been, 2) where we are, and 3) where we may be going at the UNC-CH School of Pharmacy.

If you began your Pharmacy curriculum in 1965, Ed Brecht introduced the practice of Pharmacy, Jack Wier taught you pharmacy math and Herman Thompson taught principles of pharmacy. In the next year Claude Piantadosi would have taught you biochemistry and Jack Wier would conduct two semesters of pharmacognosy. You would take zoology, quantitative chemistry, bacteriology and physical pharmacy. You would have had 10 to 12 lecture hours each week and 4 laboratory sessions. The fourth and fifth years presented physiology, pharmaceutical preparations, pharmacology (1 semester), medicinal chemistry (1 semester), prescription specialties, dispensing and two semesters of therapeutics taught by George Cocolas. You would have a one hour lecture with W. W. Taylor and a practice lab at North Carolina Memorial Hospital. Al Jowdy and/or Mel Chambers would teach you pharmacy administration. There were no "clinical pharmacy" courses and there was not an academic internship program. There was an elective each semester to allow you to individualize your curriculum. During your fourth and fifth year you would have been in a laboratory course two, if not three, afternoons each week.

The classes of 1971 and 1972 completed a curriculum sewn with seeds of change in pharmacy education. They took the first class in clinical pharmacy and had the first academic internship. Dispensing was only one semester, pharmaceutical specialties was now an elective, medicinal chemistry, pharmacology and pharmacy administration had become two semester sequences. Although laboratory instruction remained prominent, it was obvious, in retrospect, that that instructional approach was declining. Economics, public health, and pharmaceutical production would replace some of that which was lost.

During the next five years courses providing instruction regarding disease and rational treatment increased in number and quality. Pharmacists were being taught not to blindly adhere to prescriber directives, but to understand the rationale for drug selection. The number and power of therapeutic agents was growing rapidly while at the same time demand for the art of Pharmacy was diminishing. Pharmacy practice was orienting toward patients, the provision of information about drugs and to a role of provider of a health care service. The pharmaceutical product had become less the focus of the curriculum and courses were changing accordingly. Five courses focused on patho-physiology, rational drug selection, bio-pharmaceutics and pharmacokinetics, drug administration and non-prescription drug therapy. A senior dispensing lab was no longer a curricular requirement but the academic

Continued on page 14

Pharmacy Education
Continued from page 13

internship had grown to one-half of one semester on its way to one full semester. UNC-CH, as were most schools of pharmacy, was assuming responsibility for a carefully constructed, educationally sound practicum for all students.

The impact of that event upon curricular sequencing is still being felt today. The inclusion of one full semester of practical experience, given there are finite resources to provide it for all students, dictates that *two* semesters in effect are given to it. One-half of our senior students are involved in the academic internship each semester, while in the other semester, students complete their professional electives. On the surface all appears well, but in effect two adverse circumstances result. First, professional electives are taken in lump sum without the potential for "tracking" or differentiated study over the course of the entire curriculum. Electives are resultingly malutilized in preparing for selected practice roles. Second and more important, blocking the last professional year for internship means that curricular content before taught in three professional years must now be taught in two! Although the curriculum is stretched to encompass the academic internship, it is a worthwhile compromise. Most would agree that the inclusion of an academic internship in pharmacy curricula has strengthened pharmaceutical education.

The last ten years has, as mentioned, brought a strengthening of a new professional orientation to pharmacy education. We have seen that a socio-behavioral orientation has evolved in pharmacy administration. In addition to instruction in financial and personnel management, students study not only the health care system and their role in it, but they develop the communicative skills important in patient and prescriber relations, in managing people and in relations with fellow pharmacists.

What is included in the pharmacy curriculum today and why is it so constructed?

Continued on page 17

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Core Curricular Areas UNC-CH School of Pharmacy

I. GENERAL EDUCATION

Course Designation	Course Title	Semester Hours
ENGL 1	English Composition and Rhetoric	3.0
ENGL 2	English Composition and Rhetoric	3.0
ECON 10	Introduction to Economics	3.0
PHYE	Physical Education Activities	2.0
General Education Electives		18.0
	Total . . .	29.0

II. BASIC SCIENCES

Course Designation	Course Title	Semester Hours
BIOL 11	Principles of Biology	3.0
BIOL 11L	Introductory Biology Laboratory	1.0
BIOL 45	Fundamentals of Human Anatomy and Physiology	1.0
BIOL 63L	Vertebrate Structure and Evolution Laboratory	3.0
CHEM 11	General Descriptive Chemistry I	3.0
CHEM 11L	Quantitative Chemistry Laboratory I	1.0
CHEM 21	General Descriptive Chemistry II	3.0
CHEM 21L	Quantitative Chemistry Laboratory II	1.0
CHEM 41	Modern Analytical Methods for Separation and Characterization	2.0
CHEM 41L	Laboratory in Separations and Analytical Characterization of Organic and Biological Compounds I	2.0
CHEM 61	Introduction to Organic Chemistry I	2.0
CHEM 62	Introduction to Organic Chemistry II	2.0
CHEM 62L	Laboratory in Separations and Analytical Characterization of Organic and Biological Compounds II	2.0
MATH	(Math Option)	3.0
MATH 31	Calculus with Analytical Geometry	3.0
PHYS 20	Basic Concepts of Physics	4.0
	Total . . .	36.0

III. PROFESSIONAL SCIENCES

A. BIOMEDICAL

Course Designation	Course Title	Semester Hours
BACT 51	Elementary Bacteriology	4.0
MEDC 66	Biochemistry	4.0
PHPR 74	Human Anatomy and Concepts of Disease	3.0
PHYI 93	Introduction to Physiology	4.0
	Subtotal . . .	15.0

B. PHARMACEUTICAL

Course Designation	Course Title	Semester Hours
MEDC 65	Introduction to Medicinal Chemistry	2.0
MEDC 68	Medicinal Chemistry	3.0
MEDC 69	Medicinal Chemistry	3.0
PHCO 55	General Pharmacology	3.0
PHCO 56	General Pharmacology	3.0
PHAD 89	Patient Counseling and Health Behavior	2.0
PHAD 90	Financial Management	2.0
PHAD 91	Personnel Management	2.0
PHAD 99	Pharmaceutical Law	2.0
PHAR 52	Basic Pharmaceutics I	3.0
PHAR 52L	Basic Pharmaceutics I Laboratory	1.0
PHAR 53	Basic Pharmaceutics II	3.0
PHAR 53L	Basic Pharmaceutics II Laboratory	1.0
PHAR 54	Pharmacokinetics and Biopharmaceutics	3.0
PHPR 21	Drugs, the Pharmacists and the Health Care System	2.0
	Sub-Total . . .	35.0

C. CLINICAL

Course Designation	Course Title	Semester Hours
PHPR 72L	Dispensing Laboratory	2.0
PHPR 75	Introduction to Clinical Pharmacy Practice	3.0
PHPR 76	Pathophysiology and Therapeutics	4.0
PHPR 77	Pathophysiology and Therapeutics	4.0
	Sub-Total . . .	13.0
	Total . . .	63.0

Continued on page 29

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Pharmacy Education

Continued from page 14

From the most recent ACPE report of the School, the courses (and semester hours) which are to be completed for the degree, Bachelor of Science in Pharmacy follow.

Several factors contribute to decisions to include one or another area of instruction in our curriculum. Foremost among those factors is the guidance provided by the collective knowledge and experience of the Faculty together with ideas and suggestions from practitioners and students. Curricular decisions are ultimately measured by standards developed by the American Council on Pharmaceutical Education (ACPE). Every six years the School is evaluated by ACPE which judges the overall quality, including the curriculum, of the School. Guidelines are provided by ACPE by which the decision to accredit is made. That is key, for it is from an accredited school of pharmacy that students must graduate in order to sit for their licensure examination. The University plays a significant role in curricular content, especially with regard to general education in the pre-pharmacy years. Requirements for English, mathematics, foreign language, aesthetic, Western historical and philosophical perspectives are established by the University and are expectations placed upon our curriculum. Last, but certainly not least, in determining curricular content are the interests and expertise of the faculty and the resources available to the School for undergraduate instruction.

The immediate future of the UNC-CH curriculum will see the development of formally defined clerkships within the academic internship. A "clerkship" is an interprofessional experience acquired primarily in patient care settings in the provision of pharmacy services *not* associated with significant distribution, dispensing and management functions. The clerkship largely concentrates on the pharmacist's patient education and therapeutic monitoring role. We have on two occasions contended with ACPE that our clerkship was integrated throughout the academic internship and twice have been instructed by the accrediting body to restructure the internship program to provide clearly defined clerkship experiences for all students.

New electives in geriatrics, home health care, drug discovery, drug-induced disease and biotechnology will evolve. Drug information retrieval and analysis, together with information management, may move from elective to requirement. Required courses otherwise will not change dramatically except, of course, to update as health care delivery changes. What will change may be the way in which the courses are taught. Computer-aided instruction, for example, is being studied intensely in Pharmacy and across the University. Though computers will not replace "tried and true" instructional methods, the technology evolving can enhance instruction tremendously. Further effort will be made to develop small discussion groups, to promote writing and communication skills and to solidify critical professional skills. It must be recognized, however, that the present curriculum is burgeoning under the information and technology explosion. Only so much shifting and manipulation of courses can be done. Student sensed pressure to satisfy the demands placed upon them by our curriculum is perhaps understated, if said to be burdensome. Additional curriculum time appears necessary, if we are to continue to provide well-educated men or women for the State of North Carolina who can become tomorrow's pharmacists.

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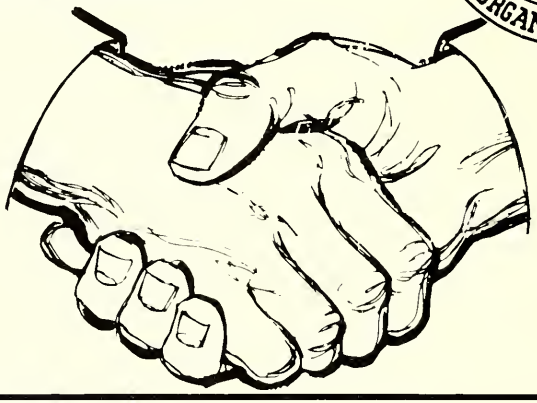

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Goldsboro, NC 27530

Just part of the buffet served in the Exhibit Program area during the 1986 Annual Convention in Greensboro.

ALBERT W. JOWDY SCHOLARSHIP FUND ESTABLISHED AT UNIVERSITY OF GEORGIA

Dr. Albert W. Jowdy, Professor and Head of the Department of Pharmacy Care Administration, retired from the faculty of the College of Pharmacy at The University of Georgia in October, 1985. Many pharmacists in North Carolina may remember Dr. Jowdy from his days on the faculty at The University of North Carolina (1950–1954 and 1960–1966) or as a practicing pharmacist at his pharmacy in New Bern (1955–1960). Al, and his wife Millie, will continue to live in Athens but are enjoying retirement which is giving them an opportunity to travel.

Dr. Jowdy was on The University of Georgia faculty from 1966 until his retirement. In addition to his academic duties, Al directed the College of Pharmacy's service programs and was known to pharmacists throughout Georgia not only as a teacher but also as a fellow pharmacist. To honor Dr. Jowdy's contributions to the College of Pharmacy and to the profession in general, the College of Pharmacy has established the ALBERT W. JOWDY SCHOLARSHIP FUND which will be used to provide financial aid to undergraduate pharmacy students at The University of Georgia.

North Carolina pharmacists who remember Al Jowdy may wish to contribute to this fund to provide sustained recognition of Dr. Jowdy's exemplary performance as a pharmacist and educator by providing scholarships for those he cares about so deeply — pharmacy students. Checks should be made payable to "The University of Georgia Foundation" and marked for the "Jowdy Scholarship Fund". Donations should be sent to the College of Pharmacy, University of Georgia, Athens, Georgia, 30602. The College will insure that Dr. Jowdy is made aware of all donations.

Continued from page 15

IV. PRACTICE EXPERIENCE

Course Designation	Course Title	Semester Hours
PHPR 92L	Academic Externship Program	12.0

NELSON APPOINTED TO GOVERNOR'S COUNCIL

Wallace Nelson, Director of Pharmacy at Chowan Hospital and a resident of Hertford, was recently appointed by Governor James G. Martin to the 20-member Governor's Council on Alcohol and Drug Abuse Among Children and Youth. "This Council will help mobilize all of North Carolina's resources to fight alcohol and drug abuse among our young people," Martin emphasized in his remarks when the Oaths of Office were administered to the Council members.

Human Resources Secretary Phillip J. Kirk, Jr. indicates that, "The Council will help both young people and parents become more aware of the struggles and decisions children and teenagers face in dealing with the availability of alcohol and drugs in our schools and communities."

The specially appointed Council will be responsible for developing new statewide programs to prevent and treat alcohol and drug abuse among young people, reviewing substance abuse laws in North Carolina, and conducting public hearings across the state.

Persons appointed to the Council include civic, religious and community leaders, parents, teachers, and students who have demonstrated interest, involvement, or expertise in child and youth issues related to prevention, intervention, and treatment of alcohol and drug abuse. In addition to training young people to make positive choices about alcohol and drugs, the Council will encourage communities to provide health alternatives to substance abuse and teach parents to help their children.

ROSEBORO PHARMACY HONORED

Tart and West Druggists of Roseboro was honored Monday August 25, 1986, by Merck Sharp and Dohme, for 78 years of service to Roseboro and Sampson County.

Tart and West was founded in November 1908 by the late D.W. Tart, who was joined in the business by his nephew, W. Latham West. Later, other family members were associated with the pharmacy, including W.A. West and his son Thomas Latham West, who currently operates the store. Matilda West, sister of W.A. West, also is affiliated with the store.

The professional award was presented by Sheryl B. Brown and Dan Miller, representatives of Merck. The award is given to less than three percent of the pharmacies operating in the nation.

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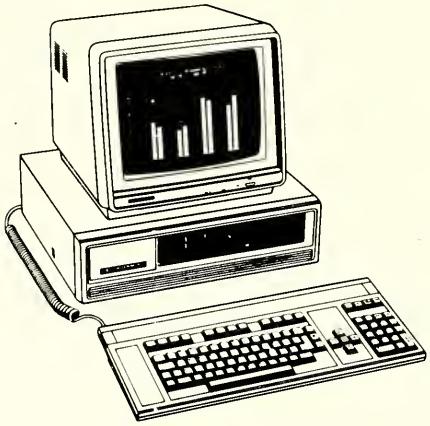

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DICKINSON'S PHARMACY

by Jim Dickinson

Honest Joe's Quality Used Drugs. "There's no such thing as ethical or 'good' diversion," testified Charles M. West, executive vice president of the National Association of Retail Druggists, on Capitol Hill December 6. It wasn't a groundbreaking statement — an FBI witness had said pretty much the same thing a month earlier — but it was still the only way to say it.

If you pushed him, retail pharmacy owner West would probably admit that somewhere along the line he, too, has considered selling diverted drugs. Samples obtained surreptitiously from a detailman or, worse, a "distributor," and dispensed to a patient are still diverted.

I'm honest, though — and I know you're as ethical as a clergyman. We wouldn't let a patient touch a single capsule or tablet that we didn't *know* was pure, straight, A-OK, from a reputable source. Would we?

But wait a minute. It's that very sense of self-righteousness and consolation that exposes the entire profession to devastating loss of hard-earned and well-deserved public confidence in the current prescription drugs diversion scandal.

As long as there's a single pharmacist who's willing to break open a sample pack of any kind and mix its contents in his stock bottle, there's a cracked door open somewhere to someone less scrupulous to slip something else past.

As congressmen and senators *and reporters* are slowly learning from the unfolding diversion scandal testimony, it's the atmosphere of unregulated, "gray" area, bent-rules ethical acceptance that makes room for the beginnings of evil. That evil at its worst includes fake contraceptives that don't work and lead to abortions or unwanted and abused children, contaminated samples repackaged in gasoline spills on garage floors or in asbestos dust in filthy old attics, and the sale of sub-potent, long-expired lifesaving medicines that can no longer save lives or that can actually kill.

If you, a fully qualified pharmacist, don't look to *see* those shocking and unthinkable evils lurking behind nice, original manufacturer pack samples, how do you expect some of the unqualified people further back along your supply-line to see them?

And that's the catastrophe that's waiting to happen to pharmacy, health care and the American people in the diversion scandal. Congress knows it. What everyone's terrified of is that the mass media will tell the whole country before the loopholes are closed off by new measures, including heightened professional awareness in addition to legislative remedies like a ban on sampling and discriminatory pricing.

It's not as if pharmacy didn't have its own self-interest to protect in opposing sampling, without having to be bludgeoned into action by the diversion scandal. Think how sampling inevitably "trains" prescribers for that approaching time when the oversupply of physicians will drive them to largescale dispensing in order to survive in the medical marketplace.

But it's "good, ethical" diversion of nonprofit hospital drugs *and* samples that's getting the attention now.

Other advanced countries comparable to our own, such as Britain and Germany, don't have U.S.-style diversion because samples and drug prices are government-controlled. We have a free market without those controls. Anything goes, and you do it, too.

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Several small prescription-oriented pharmacies are currently available for individual ownership in North Carolina. These opportunities provide the vehicle to practice pharmacy the way you were taught, while offering an attractive income and more time to be with your family. In some of these cases, financing is also available to qualified candidates. For more information write:

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COMMITTEE REPORT OF THE COMMITTEE ON PUBLIC AND PROFESSIONAL RELATIONS

COMMITTEE MEMBERS

Charlotte M. Mize — Co-Chairman, Greensboro
Lori C. Tutterow — Co-Chairman, Winston Salem
E.A. Brecht, Chapel Hill
David D. Claytor, Greensboro
Shirley A. Clifton, Raleigh
Stephen C. Dedrick, Durham
William H. Edmondson, Durham
W. Darrell Estes, Raleigh
G.C. Hartis, Winston Salem
Palmer W. King, Norlina
Randy N. Lawson, Boonville
Sonya J. Lewis, Morrisville
David M. Meyer, Eden
Dennis M. Williams, Chapel Hill
David R. Work, Chapel Hill

The NCPhA Committee on Public and Professional Relations had its final meeting on March 2, 1986, at the Institute of Pharmacy. Those in attendance were E.A. Brecht, David Claytor, Al Mebane, Charlotte Mize, and Lori Tutterow.

Two items of business from the previous year were discussed. The committee decided to table Resolution #2 (Arrangements between Pharmacists and Nursing Homes) that had been referred to the committee last year. The members felt that this resolution was unnecessary at this time. The committee also recognized the need for a comprehensive law publication which would serve as a compilation of all the laws affecting N.C. pharmacists. This publication would be available from NCPhA and could be used as a money-making project for the association. Dennis Williams and William Smith agreed to review the Michie publication *Pharmacy Laws of North Carolina* and decide which sections were pertinent.

Direct to the consumer advertising of prescription drugs is once again permissable under federal law. Our committee shares the concerns of other health care professionals that this may not be in the best interest of the public and has drafted a resolution to oppose product-specific ads.

The committee discussed physician dispensing which is becoming more prevalent in rural areas. This could be a conflict of interest as some physicians may prescribe unneeded medications. Dave Work also pointed out that physicians are not closely inspected as to compliance with safety closures and other dispensing requirements. Taking this into consideration, the committee felt it appropriate to draft a resolution which supports measures to encourage dispensing physicians to comply with state and federal pharmacy laws.

Pharmacist prescribing was discussed as a topic which the committee felt would be of increasing importance in the future. The recently passed Florida legislation allowing pharmacists to prescribe was reviewed. The committee felt that we should watch developments in Florida and encourage NCPhA to develop a position on this issue. It was pointed out that malpractice insurance is an issue that will become increasingly important to pharmacists if we get prescribing privileges.

Our committee also recognizes the importance of good inter-professional relations between pharmacists and physicians. A resolution was submitted to encourage the formation of local inter-professional committees for the purpose of discussing common opportunities for better patient care and promoting increased communications between health care professionals.

In light of the recent concern over the role of drug samples in diversion schemes, our committee feels that their sale and purchase by health care professionals should be prohibited. A resolution was written to support this position.

The committee co-chairmen would like to take this opportunity to thank the people who worked on this committee. A special thanks is due to Dave Work and Al Mebane for their ideas and assistance.

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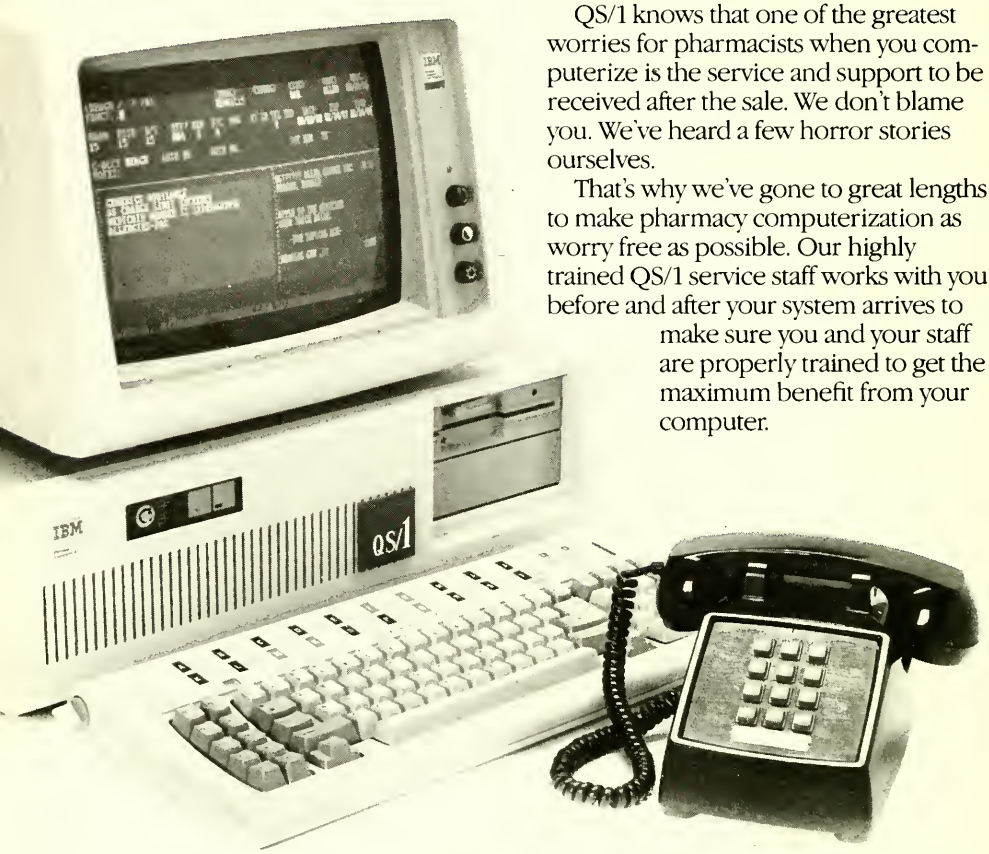

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STAFF PHARMACIST: Southeastern General Hospital, a 352-bed fully accredited facility, has an immediate opening for a staff Pharmacist. Progressive Pharmacy environment includes computerized unit-dose distribution system and IV admixtures. Position will work a D/E rotation and will also provide staff inservice education. We offer a competitive starting salary and benefit package. Interested candidates should contact: Employment Manager, Southeastern General Hospital, PO Box 1408, Lumberton NC 28358. EOE.

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Continued on page 36

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Continued from page 35

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RELIEF PHARMACIST AVAILABLE: Central & Eastern North Carolina. Contact Pharmacy Relief, PO Box 2064, Chapel Hill NC 27515 or call 919-481-1272 evenings.

WEDDINGS

The wedding of DONNA MARIE BLACKBURN and Stephen Michael Rivenbark was held August 9, 1986 in Ardmore United Methodist Church in Winston Salem. The Rev. Bill Bass officiated.

The bride is a graduate of the University of North Carolina at Chapel Hill School of Pharmacy and is pharmacy manager for Rite Aid Pharmacy in Thomasville. The groom attended Wingate College and is manager of Triad Sporting Center in High Point. The couple live in High Point.

DIANNE LoRAY CREECH and Joseph William Kapherr, Jr. were married Aug. 3 at New Hope Baptist Church, Raleigh. The Rev. Jack F. Coffey officiated.

The bride is a pharmacist at Kerr Drugs and graduated from the University of North Carolina at Chapel Hill School of Pharmacy. The bridegroom graduated from the University of North Carolina at Wilmington and is a production supervisor at IVAC Corp. The couple live in Creedmoor.

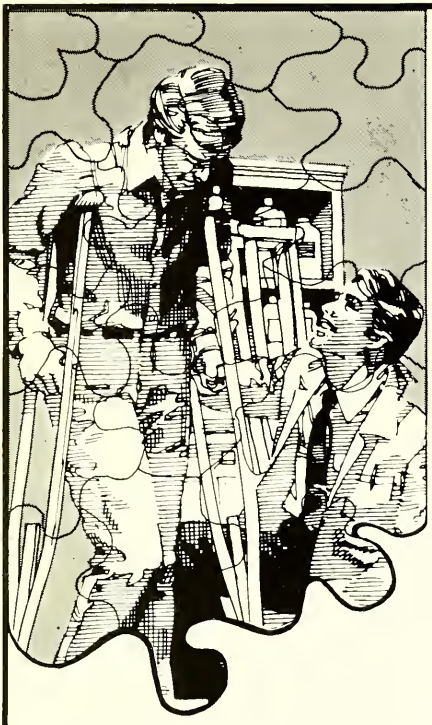
DEATHS

BEAMAN LINDSEY PINNER

Beaman L. Pinner, Asheville, died Sunday, May 18, 1986, at the age of 76. Pinner was born in South Carolina began operating a pharmacy in Asheville in 1933. He was a graduate of Newberry College and was active in civic affairs in Asheville for fifty years. He was an Associate Member of the NCPhA for 53 years. He served as president of the Asheville Drug Club in 1942 and 1946.

BRODDIE DUKE ARNOLD

B.D. Arnold, Raleigh, died Wednesday, August 20, 1986 at the age of 76. He had owned Arnold's Rexall Drugs in Raleigh for 40 years. He was a 1931 graduate of the UNC School of Pharmacy and worked in Cary, Greensboro and Raleigh before going into business as owner of Arnold's Rexall Drugs in 1940. A native of Fuquay Springs, Arnold was the father of Mrs. Harold V. Day, Spruce Pine.



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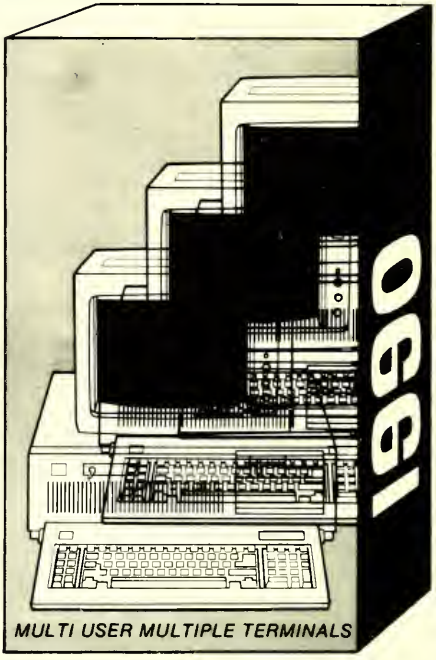

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The North Carolina Board of Pharmacy. Front row, left to right, Joseph R. Roberts, III, attorney and public member, Gastonia; William H. Randall, Jr., pharmacist, Lillington. Back row: Evelyn P. Lloyd, pharmacist, Hillsborough; Harold V. Day, pharmacist, Spruce Pine; William R. Adams, Jr., pharmacist, Wilson; and W. Whitaker Moose, pharmacist, Mount Pleasant.

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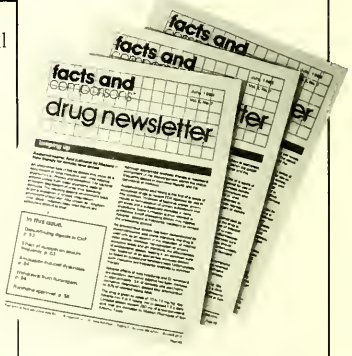

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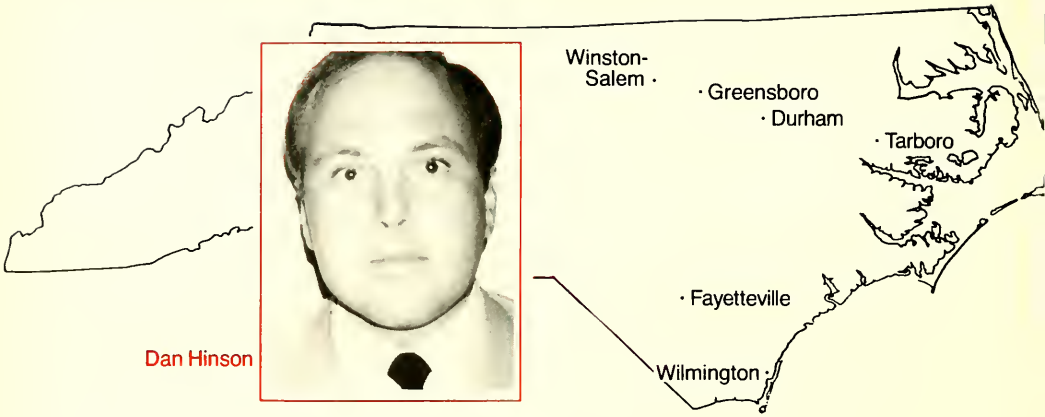

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GAPS IN PATIENT EDUCATION

by Steve R. Moore

The cost of providing patient education services remains a major determinant in their existence. Health care costs are increasingly being paid by third party payers and often it is their policies that dictate practice norms and reimbursement costs in the entire health sector. By 1979, only 32 percent of health care dollars were from direct consumer payments. Private insurance (27%) and government (40%) provided the remaining costs.[1] Of these direct consumer payments, 80% of vision care services and drugs, 75% of dental services and 36% of physicians services were included. Only 8% of hospital bills were paid directly by consumers.

Policies directed at reimbursement for patient education services by these third party payers are often difficult to determine. A recent survey showed that 96% of the 110 Blue Cross and Blue Shield Plans reported that they pay for in-house patient education services.[2] These costs, however, are not directly tabulated, but reimbursed as "allowable administrative expenses" in the overall per diem reimbursement formula. For hospital out-patient and private practice physician reimbursement, identifiable reimbursement for patient education services are included only as incidental to already covered services. Although no formal survey has been taken of other commercial health insurers, most follow BC/BS policies to maintain their competitive part of the market.

Reimbursement for government mandated programs indicate much the same pattern. Medicare policy is as follows[3] —

> While the law does not specifically identify patient education programs as covered services, reimbursement may be made under Medicare for such programs furnished by providers of services . . . to the extent that the programs are appropriate, integral parts in the rendition of covered services which are reasonable and necessary for the treatment of the individual's illness or injury. For example, educational activities carried out by nurses — teaching patients to give themselves injections, follow prescribed diets, administer colostomy care, administer medical gases and carry out other inpatient activities — may be reimbursable as a part of a covered routine nursing care. Also, the teaching by an occupational therapist of compensatory techniques to improve a patient's level of independence in the activities of daily living may be reimbursable as a part of covered occupational therapy. Similarly, the instruction of a patient in the carrying out of a maintenance program designed for him by a physical therapist may be reimbursed as a part of covered physical therapy.

Medicaid policy is difficult to determine since the 55 programs are each different, but most reimburse only in the same indirect fashion as the above-mentioned programs. This is true for both in-patient and out-patient services.

Provision of patient education services in HMO's is increasingly being documented, but at this time is still often provided in a complete package of health prevention and promotion services.[4] Reimbursers for HMO services (i.e., employers) seldom require specific patient education service components in their purchases.

In order for reimbursement to occur, there usually must be the determination made that such a cost is beneficial and effective in promoting the health of individuals and/or controlling cost. Traditionally, the federal government has funded these projects to enable it to spend its money more advantageously. Drastic cut-backs in research that will document this type of activity, as well as in overall reimbursement money, will essentially leave private insurers as the primary source of demonstration projects in health education.

Typical programs that have been studied in this demonstration area include —

Chronic Obstructive Pulmonary Disease Study — Blue Cross/Blue Shield of New Hampshire/Vermont. Study designed to determine impact of comprehensive outpatient education program on health status and health care utilization (i.e., re-hospitalizations, physician visits, prescription drug use, etc.)

Diabetes Control Demonstration Project — Center for Disease Control. Study designed to show health status and cost impact of comprehensive patient education services in a variety of settings utilized by diabetic patients.

Life-Cycle Preventive Service Study — Health Insurance Association of America. Study designed to show impact of life-cycle-related

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Patient Education

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preventive services (such as patient education) on selected morbidity indicators

Cooperative Health Education Project — Health Care Financing Administration, Henry J. Kaiser Foundation, Robert Wood Johnson Foundation. Study designed to determine effects of written patient education intervention on Medicare HMO service utilization

California Obstetrical Access Demonstration Project — Health Care Financing Administration. Study designed to show impact of prenatal services (including patient education) on mortality and morbidity infants and mothers

Over the period of the last ten years, the federal government made dramatic efforts at increasing both the supply and training of health professionals. The Bureau of Health Professions provided millions of dollars in direct support to train physicians, pharmacists, nurses, health educators and others involved in patient education. Coupled with their dollars were regulations requiring money and effort to be spent on training of preventive services such as patient education. As the supply of professionals increased, funding began to taper. Expenditures in FY'82 dramatically decreased and by FY'83 will all but disappear. As the dollars decrease, so does the ability to require specialized training. Preventive services training will often be decreased to maintain support in needed clinical sciences. Coupled with drastic cuts in student loans and decrease in other support (such as National Health Service Scholarships) both the number of students and the variety of their training experience will dramatically decrease. Patient education may all but disappear in professional training.

Given the luxury of increasing third party reimbursement for a variety of services, the health care providers and the industry which services

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them have spent funds to develop new technologic systems for patient education in recent years. With continuing hyperinflation for health services and dramatic cut-backs in government reimbursement, the ability to purchase new technologic innovations is rapidly diminishing. With decreases in potential markets, manufacturers will show a growing reluctance to spend development funds for new or innovative technologies.

The ability to incorporate patient education activities into the practice of medicine or pharmacy is often difficult. Time, space and even technologic capabilities are limitors in this endeavor. The possibility of an additional cost increment to cover this component of professional practice is one alternative. In comments received pursuant to FDA's proposal to require patient package inserts, pharmacists stated additional costs of up to one dollar to provide a PPI. Physicians postulated additional costs in talking with patients due to PPI-related problems. Although the fact that increased patient education may well mean additional patient costs, the ability to realistically predict this impact is far from evident. Comments on the costs for PPIs were often little more than pure supposition and in reality would often be recouped by retrospective readjustment of patient costs based upon experience rather than any real prospective determination based upon study and analysis.

The availability of patient education is another area of concern. Although an exact determination has not been made, the extent of physician and pharmacist provision of patient education is unknown. Part of this problem is one of terminology. Physicians and pharmacists feel that anything said in the process of the patient encounter is absorbed and would qualify as patient education. Thus, from the view of practitioners, patient education is pervasive and more than adequate. From the view of the consumer, the view is quite the opposite. One recent survey indicated that patients reported receipt of general drug information with about 50% of their prescriptions, and specific information (such as side effects) only about 10% of the time.[5] With such a small percentage of specific information being provided, the amount of usable and perceptable content may be much smaller. Thus, the critical amount of patient education may be very small from physicians and pharmacists.

Institutionalized patients face other problems. Acute care facilities overwhelmingly subscribe to the concept of patient education. A 1978 survey of 4,678 hospitals indicated 62% had at least one patient education program with written goals and objectives.[6] Long-term care facilities offer no such picture. Little is known to indicate quality or quantity of patient education that occurs in nursing homes of skilled nursing facilities. Similarly, virtually nothing is known of other long-term facilities such as mental hospitals, prisons, etc. It is especially critical to realize that many residents of long-term care facilities are at highest risk due to physical problems and high drug use, but also may be at lowest exposure to patient education services.

The extent of community patient education programs is also an unknown. Public health departments provide patient education services but often are limited in their contact with citizens or highly specialized in nature (such as family planning, immunizations, etc.). Public schools provide some health education to students though this is often dictated as health and hygiene studies that may or may not be relevant. Community service and voluntary agencies attempt broad-based efforts at disease specific (heart, cancer, muscular dystrophy, etc.) or population segments (old, young, female, etc.) but with little documented or statistically analyzed results. Increasingly, these civic or community groups are seeking affiliation with health care providers which may substantially increase both their credibility and content. Communications media (especially newspapers, television and radio) make periodic attempts at patient education, though often from an awareness rather than a behavioral viewpoint. Whatever the source, community patient education efforts are largely undocumented, untested, and uncoordinated.

Also, there is no real basis by which consumers can select a source for patient education materials from providers. There are no accepted identifiers for patient education (such as a window decal or symbol) or pre-purchase notice of service availability. Even if there is claimed provision of patient education services, a consumer has no basis of comparison between providers. Thus, availability of patient education to consumers is often difficult to determine.

The accessibility of patient education presents a varied picture. Physical patient parameters provide one area of concern. Print impaired (either sight deficient or literacy deficient) are

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Patient Education

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often unable to utilize written materials or access to these written materials. Lack of type size, color contrast or language simplicity may create difficulties for the aged, the uneducated and other individuals with sight problems. English language deficient individuals often do not have access to patient education materials. Consumers who speak, and/or read Spanish, French (Indochinese refugees) or native dialects (American Indians, Eskimos, etc.) can not necessarily utilize materials in English. The physically handicapped also lack accessibility to many patient education services. Arthritic individuals who cannot easily grasp printed materials, bedridden individuals who seldom talk with a health professional in person and persons debilitated with degenerative diseases are also often neglected in the provision of patient education materials. The mentally retarded or mentally deficient need regular patient education materials adopted to their limited capabilities and proper long-term support to insure their continuing relevancy.

Accessibility to patient education is also a problem to those individuals who have difficulty in accessibility to health services in general. This access may be controlled by several factors. Geographic maldistribution of health care providers limit both inner city and rural residents. In the same area where this geographic limits exists, often back-up resources such as libraries would also be lacking. Economic constraints also limit accessibility to patient education. Medicaid recipients often receive only those services for which there is reimbursement. Since patient education is not a mandated service, it is seldom provided as a free service. Though not covered by Medicaid, those individuals in a borderline economic area, the "medically needy," also lack access to patient education. Medical care is sporadic, often in a less than adequate fashion, and in the least expensive manner possible. Such luxuries as patient education are largely, if not totally, lacking in this medical care utilization mode.

Providers also experience problems in accessibility to patient education. Given the demands of a practice setting, time and resources to scour the marketplace for good patient education materials is simply an unknown luxury. Materials that are provided by salesmen, promotional in nature, or highly marketed often are those that find themselves in use. Well studied or analyzed criteria seldom are used as determinants for materials. Convenience, low cost and minimal hassle often suffice as reasons for obtaining materials.

Also, professionals have little practical ability in targeting patients for special patient education needs. Intuition by the professional or persistence on the part of the consumer are often the basis for selection to receive patient education. Appropriate skills in needs assessment or patient analysis remain issues unmet in professional practice. Thus, accessibility to patient education also has unmet needs.

Continuity among the patient education providers and recipients is also a major obstacle. The field of patient education is a patchwork of small systems that each see themselves as providers of patient education in a somewhat isolationist position. Among the major cells of this activity are —

- health professionals
  — physicians, pharmacists, dentists, nurses, health educators, public health officials, etc.
- health institutions
  — hospitals, nursing homes, HMO's, etc.

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- community health resources
  — libraries, schools, public health departments, media, etc.
- consumer groups
  — advocacy groups, civic organizations, etc.
- community private resources
  — voluntary agencies (diabetes, heart, cancer, etc.), industry, etc.

Within each cell there is often lack of coordination. Physicians and pharmacists often do not provide continuity for the patient. And the lack of communication between components of different cells often provide the consumer with incomplete, inappropriate or even contradictory information. Since each particular cell or component of each cell sees themselves as preeminent or complete in their impact on the consumer, often little coordination between competing forces occurs. The result is a patient education system of inconsistency and gaps but with little to really bridge these components into a unified system.

The acceptibility of patient education materials and programs is another area of concern. The consumer or the recipient of the education effort is often at the greatest disadvantage. The consumer has little input into the type, extent or even cost of services provided by health professionals. Little feedback or evaluation of the effort is undertaken by providers and due to the traumatic nature of the consumer-provider encounter, little effective information may actually be transferred. As variable as the consumer-provider encounter is in a physicians office or pharmacy, institutionalized patients have even less say in their encounter. Bombarded by multiple white-coated individuals, patient education, even when billed as an add-on service, gets little input or control by the patient.

Producers of printed materials also seek little input for consumers in the development of materials. Although marketing analysis may occur, producers of patient education efforts hold control of the technical content and presentation

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format far from the input of the consumer.

Again, in community-wide resources in patient education, the coordination problems present problems in the acceptability of effort. Population targeting, type and range of materials, depth of involvement and multiple other facets of production and presentation do not allow an effort with overall positive and targeted impact.

Perhaps the greatest concern in the acceptability of patient education materials is client-specific materials. With various on style, content or presentation that are necessitated by a defined population, these materials are often lacking. Specific high priority populations include —

- elderly
  - — special needs for high risk drugs, warnings on side effects, presentation with appropriate type size and coloring, long-term use problems and understandable information
- pediatrics
  - — special needs for dosing instructions, drugs that may affect development and storage and administration of drugs
- pregnant women
  - — special needs for drugs that may affect development of fetus, carrying fetus to term or health of mother and fetus
- nursing mothers
  - — special needs for drugs that affect production of milk or might be passed through breast milk to infants
- sexually active youth
  - — specific needs for drugs that effect conception, sexually transmitted diseases or physical performance
- disease specific
  - — special needs for drugs that affect certain disease states and an understanding of both their possible effects and limitations on the diseases

Specific remedies for dealing with specific populations have been formulated for ethnic minorities and, as such, may be beneficial in developing strategies for other special populations.[7]

Finally, the acceptability of patient education is often compromised by the lack of two-way communication between the provider and consumer. Material is directed to the consumer by the provider. Little information comes from the consumer to the provider. Information, in and of itself, is not education and other accomplishes little retention, usefulness or effectiveness on behalf of the consumer.

The quality of patient education materials provide yet another area of gaps in the system. Printed materials have no accepted standards for content, format or presentation. FDA has studied format and content of printed materials,[8] but no standards are established by medical writer or publishing groups. While diversity may be good in the marketplace, this diversity also results in less than appropriate content and format in publications that the consumer may not be able to judge.

The practice of patient education has little that is generally accepted by all participants. Classic delineations of health education serve as good guidelines for standards of practice,[9] and additional delineations have also been undertaken.[10] However, these are little known or followed by the great number of individuals or organizations involved in the field. Haphazard or self-serving efforts are far more prevalent than well controlled and managed efforts.

The preparation and training of individuals, as well as job competencies for involvement in patient education, are not well established. One government contract undertook a laborious process of defining job competencies for health educators.[11] The contract resulted in a description of a health educator, but not necessarily of all the other health professionals with defined expertise who are also involved in patient education. Additionally, a compilation of policies and resolutions by professional organizations shows the diversity of perceptions and conceptualizations in the health field.[12] The interlinkages between the various professions in the field of patient education are often nebulous, overlapping or not understood. Conflicting information and directions are often the result. Even the various education efforts for health professions in colleges and universities have no consistency in either content or depth of training.

With the provision of patient education, there is also little concensus or standards of acceptable outcome. In answer to provisions of PL95-83, standards were developed for community health services, including health education. These standards were submitted to Congress in September 1979. Additionally, the Surgeon General presented priorities for accomplishing preventive goals in the country.[13] The health planning establishment that was established

(Continued on page 13)

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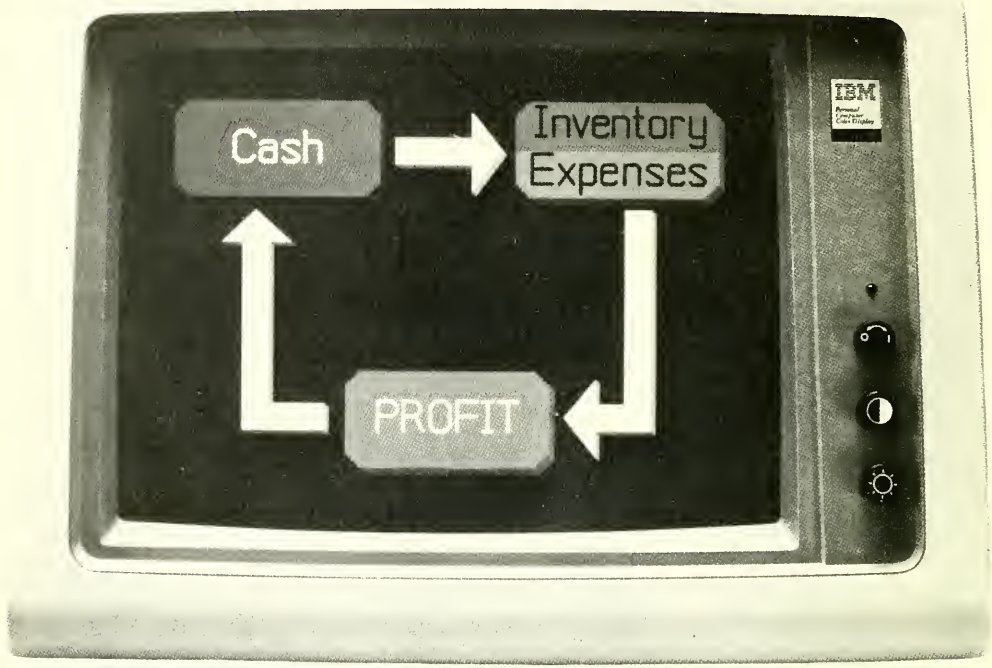

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Patient Education

(Continued from page 11)

through PL93-641 also included health education as one of its top priorities. Some 23 of 45 state health plans included goals related to patient education. Despite all of the attempts to put some order in the processes of patient education, there remain few generally accepted and measured outcomes. Even qualification of established goals is seldom undertaken.

Gaps in the Provisions of Patient Education Services

I Cost

limited reimbursement for patient education by third party reimbursers

limited availability of funding for demonstration projects in patient education

limited availability of funding for professional training that focuses on patient education

limited develoment funds for technologic systems research

presence of additional costs to consumers for the receipt of patient education services

lack of knowledge of real costs for providing patient education in professional practices

II Availability

lack of supply of pharmacies providing patient education

lack of supply of physicians providing patient education

lack of institutional patient education programs

— long term
— short term

lack of community patient education programs

lack of parameters by which consumers can select providers who provide patient education.

III Accessibility

limited physical patient parameters

— print impaired
language deficient
physically handicapped
mentally retarded

limited geographic parameters — inner city
rural

limited financial parameters

Medicaid recipients
medically needy

limited knowledge of professionals of range and nature of patient education materials available in marketplace

limited ability of health professionals to properly target patients in need of patient education

IV Continuity

lack of linkages among health professionals

lack of linkages between institutions and community

lack of linkages between profit and non-profit sectors

lack of linkages between public and private sectors

lack of linkages between health professionals and consumers

lack of linkages among public sector groups

lack of linkages between educators and health professionals

V Acceptability

lack of input by consumers into delivery of patient education by health professionals

lack of input by consumers into material development by publishers

lack of input by consumers into industrial efforts of patient education

lack of coordination of community resources in patient education

lack of client-specific education for special populations —

— elderly
pediatrics
— pregnant women
— nursing mothers
— sexually active youth
— disease specific

lack of two-way communication in patient-provider encounters related to patient education

(Continued on page 14)

VI Quality

lack of accepted standards for print materials on patient education

lack of source for coordination of effort and standards of practice in patient education

lack of acceptable training standards for providers of patient education

lack of acceptable practice standards for providers of patient education

lack of acceptable standards for quality of outcome of patient education

lack of acceptable standards for research efforts in patient education

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On bare feet smarting from gravel in the back alley, the boy, not quite ten years old and small for his age, gingerly picks his way to the screen door and lets himself into the rear of the drugstore. As always, he pauses and sniffs the air, luxuriating in the exotic aroma unique to pharmacies of the twenties. The pleasant smell permeates the whole store, but it is particularly rich and heavy, almost palpable, in the back room where prescriptions are being compounded.

Passing through, the boy greets his uncle and is not surprised when the old man doesn't notice him. He rarely ever does. His uncle, talking crops with a farmer waiting for his prescription to be filled, bends stoop-shouldered over a pill tile. He uses a spatula to divide into twelve equal parts the rectangle of powder he has shaped, composed of three different drugs, weighed and mixed together. A familiar sight to the boy. On the counter is a stock box stacked with powder papers. Each paper will receive its individual dose of the mixed powder before the papers are folded to fit into the prescription box labeled with the doctor's directions.

Leaving the back room, the boy glances about the front of the store, but does not see his father. He approaches the marble-topped soda fountain. A customer is watching the soda jerk vigorously stir a Coke just concocted by pumping two squirts of Coca Cola syrup into a six ounce glass, adding chipped ice before filling the glass with carbonated water from the draft arm.

"Your daddy's outside sitting on the bench. Said his feet were killing him," he says.

"Thanks," the boy replies. He notices that, sure enough, the clerk's jaws do puff out, making him look like a squirrel with its mouth full of hickory nuts, the way the boy's daddy, tired and put out with the worrisome soda jerk, had once described him to the boy's mama. She listened patiently, waiting for her husband to get it all out of his system: "I keep telling that boy not to stir his Cokes so hard and so *long.* No wonder customers are always calling me when I'm in another part of the store, wanting me to make them a Coke. They like mine because I don't stir all the carbonation off. I try to tell him that a quick swish or two is all the mixing it takes. The more you stir the flatter it gets. But I can't make anything sink into that pea-brain of his."

Approaching the front door, the boy catches sight of his father sitting on the end of the bench with the drugstore slogan painted across its length. The letters, faded with age, seem to whisper the message their once bright red color used to shout: IF IT'S GARFIELD'S IT'S GOOD.

The boy's father, absorbed in conversation with an old friend in sagging blue overalls who stands over him, leaning close, doesn't see his son in the entrance, waiting under the revolving wooden blades of the fan supposed to keep the flies out.

The boy has been taught that it's not polite to interrupt when someone is talking. So he waits. And listens.

"I've got a birthday coming up Monday," the boy's father says. "It's hard for me to realize, but I'll be fifty. And I don't want but one thing for my birthday. All I want is for one of those genies to appear and grant me one wish. Not three, just one wish."

"What would you wish for?" the man grins.

"Well, sir, I'd wish for a dollar for every grain of sand in the Atlantic ocean," says the boy's father, blue eyes glinting.

"Think that would be enough, do you? What in the world would you do if you did have all that money?"

The boy's father cocks his head and, in the soft, slightly nasal voice he unconsciously slips into when he is about to take someone into his confidence, says, "The first thing I would do would be to kick one helluva lot of asses."

The boy is shocked with disbelief. He has never heard his daddy talk like that before and he doesn't understand what would make him say such a thing. He turns, runs through the drugstore and out the back door, the ten cents he was going to ask for to go to the picture show forgotten.

HOME HEALTH CARE GUIDE PUBLISHED

A Hospital Pharmacist's Guide To Home Health Care, published by the American Society of Hospital Pharmacists, and edited by James C. McAllister, III, is now available. The 190 page publication is a compilation of more than 30

(Continued on page 31)

We've All Heard These Excuses

"I don't have time today."

"I forget how much to take."

"I don't like the way it makes me feel."

"I'm feeling better so I stopped taking it."

We've all heard patients' excuses for failing to take medicine as prescribed and we're all aware of the consequences: an estimated 125,000 deaths each year, hundreds of thousands hospitalized, millions of workdays and billions of dollars lost.

So the American Pharmaceutical Association and the Pharmaceutical Manufacturers Association have joined forces in a nation-wide public service campaign to educate the more than one-third of us who fail to take our medicines as perscribed.

We invite you to join us.

The campaign consists of TV and radio public service messages sent to stations throughout the U.S. and a 5-minute film which is available as a TV talk-show vehicle and as a curtain-raiser for talks to community groups. Also available are inserts for prescription packages and posters.

Contact your association for details.

Please join us. We're telling Americans that their health is in their hands. ***But their education is in yours.***

American Pharmaceutical Association

2215 Constitution Ave. NW
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Pharmaceutical Manufacturers Association

1100 Fifteenth St. NW
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RECIPE FOR SOUND SLEEP: ALCOHOL NOT AN INGREDIENT

by Milton K. Erman, M.D.
Associate Professor of Psychiatry
Southwestern Medical School
University of Texas,
Health Science Center at Dallas

Insomnia can drive some people to drink, but downing a few hot toddies before bedtime can make a good night's sleep even more elusive.

Consuming two — or three or four — shots of alcohol may "knock out" the weary insomniac, but that nightcap may damage the quality of sleep for the rest of the night. And in some cases, alcohol can trigger life-threatening health problems.

Alas, the before-bedtime cocktail is too often among the misguided but well-intentioned home remedies for insomnia. Experts differ on exactly the amount of alcohol that will affect sleep, but some believe that even one shot of liquor taken an hour or less before going to bed disturbs the pattern of slumber, making it light, unsettled and less than refreshing.

The person initially lulled to sleep by drink may sleep soundly for the first few hours, but then awaken or sleep poorly. The sleeper may also experience nightmares and feel unusually tired the next day. People who drink regularly may experience nightmares on nights that they refrain from alcohol.

The potential for abuse of this insomnia "home cure" is high because the amount of alcohol needed to invite drowsiness increases rapidly in a short time with regular use.

WHAT IS INSOMNIA?

As many as 33 percent of adults in the United States report that they suffer from occasional sleep problems, and an estimated 10 million adults annually seek doctors' advice about the problems.

Insomnia is defined as the complaint of unsatisfactory sleep, and it can appear as difficulty in falling asleep, difficulty in staying asleep, or unrefreshing sleep.

This lack of sleep usually causes the person to feel irritable, fatigued and uncomfortable during the day. Indeed, a major consequence of insomnia is that it may impair daytime functioning.

Insomnia is not a disease, but the sign of an underlying problem — often one that deserves medical attention.

Insomnia—3 Paths to Daytime Sleepiness

TYPE	CAUSES	DURATION	THERAPY
Transient Insomnia	Minor situational stress such as jet lag or impending surgery	2 to 3 days	"Stick it out" until it goes away Sleep hygiene counseling Short-acting sleep medication for a few nights
Short-term Insomnia	Situational stress often related to work, family or physical problems	Up to 3 weeks with possible recurrent episodes	Sleep hygiene counseling Intermittent small doses of short-acting sleep medication
Long-term Insomnia	Underlying medical or psychiatric conditions Chronic drug or alcohol dependence Sleep apnea Spasmodic leg movement during sleep And others	Indefinite	Good sleep hygiene Stress-reducing procedures Biofeedback A short trial of sleep-promoting medications in combination with psychotherapy or behavioral therapy

ILLUSTRATION — THE UPJOHN COMPANY

Most normal sleepers have probably experienced *transient insomnia* — a disruption in sleep for one to three nights. Jet travel across time zones or hospitalization for elective surgery may induce transient insomnia.

Short-term insomnia, lasting from three nights to three weeks, may be caused by personal problems such as the death of a loved one or by loss of a job. Although this type of insomnia usually disappears a few weeks after the specific stress lessens, sleep medications are often helpful in the interim.

Long-term insomnia, lasting more than three weeks, may stem from chronic medical illness, depression or other psychiatric problems, alterations in biological clocks, chronic drug or alchohol misuse, anxiety about sleep, poor sleeping habits, or a sleep disorder such as *nocturnal myoclonus* (thrashing of the legs during sleep) or *sleep apnea* (a breathing problem).

ALCOHOL DOES BATTLE WITH SLUMBER

Alcohol is a major cause of insomnia in part because it disturbs the Rapid Eye Movement (REM) cycle of sleep.

REM sleep appears about 80 to 90 minutes after the onset of sleep and the first REM phases lasts about 10 minutes. During a typical night's sleep, REM sleep will recur four or five times, increasing in duration each time, with the final REM cycle lasting up to 40 minutes. REM sleep can occupy a total of two hours during eight hours of slumber.

But for the sleeper who has had a few drinks of alcohol before retiring, alcohol in the bloodstream acts as an enemy to REM, fighting off the cycle.

About five hours after sleep occurs, as the body eliminates the alcohol, sleep becomes disturbed for the rest of the night. One reason for this disturbance is that REM sleep "rebounds" and can return with a vengeance to intrude on the other cycles and deprive the body of deep, restful sleep.

For several nights after a habitual drinker stops drinking, the person may suffer from nightmares stemming from REM sleep rebound. An alcoholic on a drinking binge may suppress REM sleep for so long that it will rebound when the individual is awake. Researchers have theorized that delirium tremens, or d.t.'s — hallucinations and muscle jerks — are actually portions of the REM cycle in action while the alcoholic is awake.

ALCOHOL MAY TRIGGER FATAL CONDITION

In many people, alcohol also is believed to trigger or aggravate *sleep apnea,* a disorder characterized by snoring and periods of not breathing during sleep. This potentially life-threatening problem is common and is seen more frequently in older people. Sleep apnea is especially dangerous to those with a history of pulmonary or cardiac disease.

The disorder is defined as frequent halts in breathing, lasting from ten seconds to as long as three minutes. Sleep apnea is another roadblock to a good night's rest because the sleeper, though typically unaware, is awakened briefly but repeatedly as he gasps for breath. These stirrings, occurring perhaps hundreds of times a night, fragment the flow of the sleep cycles.

Some degree of sleep-related respiratory impairment affects an estimated 20 percent of the population, and 60 percent of men over 60 years old. Men who are overweight and snore are more apt to have sleep apnea.

A group of my colleagues, sleep experts in Gainesville, Fla., studied 20 healthy men ranging in age from the 20's to the mid-60's. The men were given four shots of vodka less than an hour before bedtime. Their sleep was monitored, and the episodes of sleep apnea were significantly longer and five times more frequent than for the same men when they had not imbibed alcohol.

Alcohol worsens the condition because it relaxes the muscles in the throat and suppresses the awakening mechanism, adding to the time it takes for a sleeper to stir and take a breath.

Sleep apnea can trigger potentially fatal conditions, including an erratic heartbeat, severe drops in oxygen levels in the blood and a rise in blood pressure. For those already suffering from cardiac and pulmonary disease, even moderate drinking before bedtime presents a risk. This effect of alcohol may be even greater in men than in women.

FALLING ASLEEP THE OLD-FASHIONED WAY

Sleep is integral to keeping the body a humming machine. The body's growth hormone,

(Continued on page 21)

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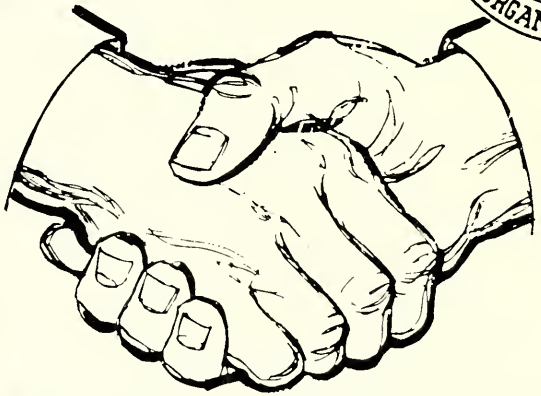

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ILLUSTRATION—THE UPJOHN COMPANY

a secretion linked to the formation of bone and red blood cells, is released during deep sleep, and REM sleep is believed important in maintaining memory.

Insomniacs in search of sleep are sometimes tangled in a Catch-22. The more worried the weary person is about falling asleep, the more tossing and turning is likely to follow.

The caution against using alcohol as a self-help for insomnia does not rule out common-sense steps that may alleviate the problem. Of course, if sleeplessness persists, a trip to the doctor is in order to determine the root of the problem and find a treatment.

For an occasional problem:

- Instead of taking an alcoholic drink, try a glass of warm milk or a light snack.
- Exercise during the day or in the early evening but avoid strenuous activity too close to bedtime, as this may be more stimulating than relaxing.
- Avoid caffeine and nicotine before retiring — both are stimulants.
- Read, listen to music, watch television or do anything else that invites drowsiness. Avoid going to bed before feeling sleepy.
- Try to get up at the same time every day to establish a solid sleep and wake cycle.

And, if all else fails, sometimes the oldest home remedy — counting sheep or any other object — may prove distracting enough to lull to sleep all but the anxious sheep rancher.

For those who want more information about insomnia, the booklet "What You Should Know About Insomnia" can be obtained by writing to INSOMNIA/UPJOHN, Dept. BY, Box 307, Coventry CT 06238.

For the location of nearby sleep disorders centers, write: Association of Sleep Disorders Centers, P.O. Box 2604, Del Mar, CA 92014.

DRUG DIVERSION AND ITS IMPACT ON PHARMACY

by
J. Paul Whitt, B.S.
and
Edward H. Clouse, Ph.D.

In recent years, drug diversion has become a major issue in modern pharmacy practice and has been the subject of several federal investigations. More and more, the public is reading of these investigations and the many indictments of pharmacists, physicians and others who are involved in illegal procurement of legend drugs.

Examples of drug diversion include:

1. bulk resale of drug products to redistributors by hospitals and other institutions that use their nonprofit status to purchase drugs at preferred discount prices;
2. the sale of samples by physicians to pharmacists or directly to their patients;
3. the sale of out-dated drugs that have been repackaged and often relabled omitting lot numbers and expiration dates;
4. counterfeit drugs, both foreign and domestic;
5. export drugs, which are sold to foreign buyers but reshipped back to America; and
6. stolen merchandise

Bulk Resale of Drug Products

A number of companies are in operation across the United States which purchase pharmaceuticals from hospitals and other nonprofit institutions then resell them to wholesalers and community pharmacies. These "redistributors" solicit hospital pharmacies to buy certain pharmaceuticals in excess of their needs and then purchase from them at a specified mark-up. The pharmacist who arranges these transactions may be offered a kickback to make the proposal more attractive. Retail pharmacists become involved when redistributors approach them with the diverted drugs and offer them at a cost lower than the cost at which a wholesaler could supply them.

Opponents to the "redistributor" (also referred to as the gray market) cite a number of reasons for their opposition. These include:

1. Product recall. There is no means to recall diverted drugs since this practice is not regulated.
2. Handling and Storage procedures. Proper handling and storage during redistribution so that product quality is not compromised is questionable.
3. Expired drugs. There is no way to protect against relabeling and redistributing expired drugs.
4. Unfair price differentiation. Nonprofit institutions receive discounts due to their non-profit status.

In 1976, the Supreme Court issued an opinion on the interpretation of "own use" in Section 13 (c) of the Robinson-Patman Act, known as the Nonprofit Institutions Act, after thirteen drug companies appealed the ruling of a lower court on this issue. The Portland Retail Druggists Association had sued Abbott Laboratories and twelve other drug companies in federal court because of preferential discount pricing practices. The result of this lawsuit was a legal precedent set by the Supreme Court which restricts nonprofit hospital pharmacies from selling medication to the general public under the nonprofit status of the pharmacy.

Diversion has become so widespread that a special house Subcommittee has been established to review the scope of this problem and to recommend legislation that will, hopefully, curtail diversionary activity in the future.

The House Subcommittee appointed to look into drug diversion questioned several Pharmacy Associations about possible legislative remedies and heard testimonial responses at its final hearing on December 6, 1985. At this hearing, the National Association of Chain Drug Stores (NACDS), the National Association of Retail Druggists (NARD), and the National Wholesale Druggists Association (NWDA) cited preferential drug pricing to nonprofit institutions under Section 13 (c) of the Robinson-Patman Act as the primary cause of drug diversion. The American Pharmaceutical Association (APhA) joined these groups to recommend that the scope of Section 13 (c) (the Nonprofit Institutions Act) be narrowed and that the "own use" requirement be more strictly defined. The American Society of Hospital Pharmacists (ASHP) does not see changes in Section 13 (c) as a solution to the diversion problem, but instead supports legislation imposing criminal and civil sanctions on those engaged in bulk resale of pharmaceuticals as well as anyone who knowingly deals with diverted drugs.

In August, 1985, the U.S. Attorney's Office in Atlanta, Georgia, announced indictments of numerous physicians, pharmacists, wholesalers

and drug representatives nationwide. The indictments resulted from an undercover FBI operation called "Pharmoney" where discounted drugs sold to hospitals and physicians and drug samples were being resold illegally to wholesalers or practitioners. A number of the criminal cases have already resulted in prison terms.

Samples

For many years, manufacturers of legend drugs have encouraged their sales representatives to give samples of their products to physicians, pharmacists and other health professionals for use in their practices. Some of these health professionals are dispensing these drug samples to their patients and receiving remuneration for them.

A major concern about this type of drug diversion is that of the storage and handling procedures sales representatives abide by in transporting these drugs from one office to the next. The quality of the product may be compromised when exposed to extreme temperatures that are often reached in the representatives' cars.

Drug manufacturers often package and label their products as samples if they are intended to be used for that purpose. However, most pharmacists who dispense these samples as typical legend drugs will remove the word "sample" from the tablet or capsule by using alcohol, acetone, or some other solvent. Dispensing these drugs is illegal because they are now considered to be adulterated.

Currently, no regulation of drug sampling exists. Usually, sales representatives do not need to be licensed and are subjet to little or no record-keeping requirements, except for controlled substances. Many pharmacy associations are opposed to drug sampling and are actively involved in developing legislation to prohibit this practice in the future.

Expired Drug Products

Repackaging expired drugs and selling them to consumers is a form of diversion that poses an even greater health concern. Drug products that have expired are considered to have lost at least 10% of their labeled potency and are not to be dispensed. A decrease in therapeutic activity of the product and/or the appearance of a toxic substance may occur. If consumed, the expired drug product could compromise the health of the consumer.

Counterfeit, Export and Stolen Drug Products

Counterfeit drugs, exported to other countries and then reshipped to the United States for sale, and stolen drugs represent other areas of drug diversion that have been uncovered by recent investigations. These drugs may not meet United States Pharmacopeia standards if manufactured outside the U.S., their stability may be compromised if improperly handled or stored or they may be adulterated in some manner. For these reasons, dispensing these medications to the general public pose additional health hazards and should be discouraged.

In the fall of 1985, testimonials from professional pharmacy and trade organizations were heard by the House Energy and Commerce Subcommittee on Oversight and Investigations on drug diversion. Responding to the Committee's questions on possible legislative remedies were representatives from APhA, ASHP, the National Association of Boards of Pharmacy (NABP), NACDS, NARD, NWDA and the Pharmaceutical Manufacturers Association (PMA). The major topics for discussion at the final Subcommittee hearing on December 6, 1985 included reimportation of prescription drugs, manufacturer sampling, institutional diversion and wholesaler accountability.

The pharmacist organizations, including NABP, came out strongly in favor of an absolute ban on sampling by the drug manufacturers. All these groups supported, to some extent, alternatives to the current practice including a "coupon" system or a "trial prescription" program. PMA and NWDA opposed legislation prohibiting sampling and the alternatives recommended by the pharmacist organizations. NWDA supported restricting sampling to the promotion of new products. PMA opposed restrictions on sampling, but would support legislation prohibiting any person from buying or selling samples. All the groups favored a ban on the reimportation of prescription drugs.

Stephen Sims, Special Assistant to the Oversight Subcommittee, outlined the possible legislative agenda for addressing the problem of drug diversion at an APhA seminar on December 17, 1985. Sims thought it likely that new legislation would: 1) prohibit the reimportation of drugs, with limited exceptions; 2) make it illegal to buy samples; 3) make routine bulk resale of drugs illegal for all institutions (for profit as well as non-profit); and 4) increase wholesaler accountability, requiring documentation to show that drugs purchased have passed through the

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Drug Diversion

(Continued from page 23)

normal channels of distribution.

The House Subcommittee on Oversight and Investigations released a report on April 27, 1986 entitled "Dangerous Medicine: The Risk to American Consumers from Prescription Drug Diversion and Counterfeiting." In that report, recommendations banning the reimportation of drugs, prohibiting drug sampling, and imposing strict penalties on health care facilities that engage in the bulk resale of drug products in the "gray market" were outlined. The report also reflected the Subcommittee's opinion that the Non-profit Institutions Act [Section 13 (c) of the Robinson-Patman Act] should be reviewed by Congress.

The public's health is the primary concern with a spread of diverted drugs into the nation's drug distribution system. A more subtle concern that has a potentially significant impact on the pharmacy profession is the adverse publicity that pharmacists who use diverted drugs are receiving. Consumers have entrusted pharmacists with their health care for many years. Surveys conducted recently indicate that the majority of people in the U.S. regard pharmacists as highly trusted health professionals. These surveys also revealed that most people relied more heavily on and followed a pharmacist's advice more often than they followed a physicians's. Pharmacists who use gray market drugs in their practice may be regarded as uncaring as well as avaricious. The loss of the consumer's faith, trust and respect, which is a cornerstone of the profession, could be a serious indirect consequence of this pervasive problem of drug diversion.

References available upon request.

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Using Medicines Safely: A Message For Older Americans

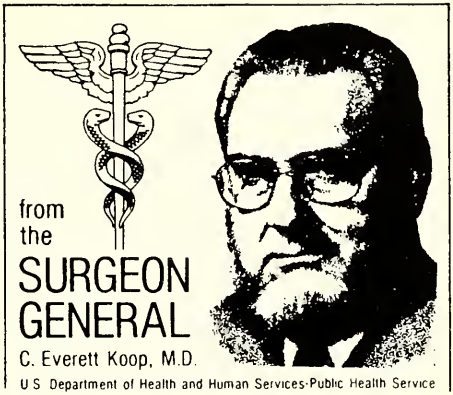
The same medicines that we take to cure our illnesses, speed up our recoveries and make us feel better can cause serious health problems if not taken carefully. Medicines work only when people use them as directed and coordinate them with what they eat and drink and with other medications they are taking.

Due to the quantity of medicines they take, the difficulty of taking them as prescribed, or the effects of the drugs, older Americans have a great problem complying with their medicine schedules than the overall population. Because older Americans generally take more medication than other age groups, they also run a particularly high risk of problems resulting from interactions among drugs. Forty percent of the people who encounter adverse reactions from taking multiple drugs are over 60.

There are many easy steps older people can take to learn more about their medicines and how their medication schedules should be followed. The most important thing we can do is *talk* to our doctors and pharmacists and listen to their answers. When your doctor prescribes a new drug, be sure to tell him or her what medicines you already are taking, including over-the-counter remedies such as aspirin, laxatives, antacids and so forth. This will help ensure that your new prescription does not react adversely with other drugs you are taking.

Find out the name of the new medicine (both the brand name and the generic) and ask what it is supposed to do. Ask what foods or beverages you should take it with and what foods, drinks or activities you should avoid while you are on it. Find out if there are likely to be any side effects and, if so, what they may be and what you should do if you get them. Tell your doctor about any adverse reactions or allergies you have had to medicines in the past.

To have their intended effect, medicines must be taken at certain intervals in certain strengths. Follow you doctor's recommendations and schedule for taking your medicine. If you have trouble taking your medicines as directed, whether because of an inconvenient schedule, hard-to-follow instructions or just an expensive prescription, let your doctor know. He may be able to make your treatment easier to follow or prescribe less expensive drugs. Don't hesitate to ask if generic drugs are available for your particular needs.



Never stop taking your medicine without talking with your doctor first. Besides not giving you the medical treatment you need, it could also cause problems down the line. For example, if your doctor believes that you're taking your medication properly, when he examines you he may see problems he thought the drug would alleviate. As a result, he may prescribe a stronger medicine than you need. Be honest about your compliance.

The other person who can help you with your medication is your pharmacist. Talk to your pharmacist about prescriptions you are getting, and ask if there are any special instructions for taking it or any special requirements for storage, such as keeping it in the refrigerator. If you are taking more than one medicine, ask your pharmacist about aids to help you organize your medication schedules.

If you find labels are hard to read, ask for larger type. Make sure you understand the exact directions for taking your medicines. You should discuss such statements as "four times a day" or "as needed" to understand exactly when to take them. You can also ask your pharmacist to fill your prescriptions in easy-to-open containers instead of those with childproof caps.

It's a good idea to make a list of the medicines you take and carry it with you. Then you can show it to your doctor and pharmacist when you are getting a new prescription drug or need a recommendation on over-the-counter remedies you may be purchasing. Besides understanding what you are now using, you should take inventory in your medicine cabinet and get rid of old medicines. Throw out all over-the-counter drugs whose expiration dates have passed.

(Continued on page 26)

Using Medicines

(Continued from page 25)

Your pharmacist can tell you how to keep prescription drugs. Take any medicines that are hard to identify to your pharmacist, who can tell you what it is and if it is still effective.

It is important to store drugs in a cool, dark location to preserve their potency. Humidity and heat often can weaken drugs, so avoid storing them in bathroom cabinets or near kitchen stoves.

Be sure to throw away any medicines that friends or family members may have given you. Some people like to share their medication with friends whom they believe have the same problem. While they mean well, sharing medicine is dangerous because people react differently to medicines, even if they have the same condition.

Healthy older people use medicines safely. Make sure your medicines do for you what they are supposed to do: Help you lead a longer, healthier and more active life.

Dear Mr. Mebane:

In the near future, the Pennsylvania Pharmaceutical Association plans to devote one issue of *The Pennsylvania Pharmacist* to the Association's Pharmacy Crime Prevention Program. The issue will feature articles on preventing crime against pharmacists and pharmacies. We need your assistance to put together a Journal which will contain a wide variety of articles on the subject. If you or your association is able, we would appreciate your submitting an article suitable for publication in the PPA Journal that would be germane to preventing crime against pharmacy.

PPA is the only pharmacy organization which offers a reward for information leading to the conviction of any person committing a crime against a pharmacist or pharmacy in Pennsylvania, but we find that we must constantly remind pharmacists to cooperate on their own behalf. Your contribution of an article

(Continued on page 32)

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On remodeling his store, Kinard's Pharmacy in Greensboro. We are glad to have supplied some of the new fixtures for this project.

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LOCAL NEWS

NORTHEASTERN CAROLINA PHARMACEUTICAL SOCIETY

The Society met Wednesday, August 13, 1986 at Cobb's Restaurant in Williamston, for the fourth meeting of the year. Mr. Rufus Walston, Roche Laboratories, sponsored a program on "Update on Drug Interactions" by Jim Worden, Pharm.D. The Society voted to donate one hundred dollars to the Pharmacy Foundation of North Carolina and one hundred dollars to the Consolidated Student Loan Fund of the NCPhA in memory of John Stevenson of Elizabeth City, a former president of the Society. There were forty four members and four guests present.

Michael Adams, Secretary-Treasurer

GASTONIA

Eckerd Drugs on Franklin Street was robbed of an undisclosed quantity of drugs and the robber was arrested less than a mile from the store shortly after the holdup. The suspect entered the store, pulled a handgun and demanded drugs be put in a brown paper bag. The robbery took place on the weekend of August 8, 1986. The suspect was out on bond in connection with another robbery charge.

JONESVILLE

D-Rex Drug Store was the scene of an armed robbery Tuesday, August 5, 1986. A man made employees lie on the floor while he fled with Demerol, Dilaudid and other narcotic drugs. A suspect was arrested in Spindale late in August and charged in the robbery. Police say he is a suspect in similar robberies in the Carolinas and Virginia.

CHAPEL HILL

Two armed men robbed Glen Lennox Pharmacy of about $500.00 in drugs Saturday, July 26, 1986. The men entered the store about 1:30 pm and requested specific controlled substances.

RICH SQUARE

Hollingsworth Pharmacy was entered by burglars late Thursday night, August 21 or early Friday morning and narcotic drugs, cash, and blank checks were stolen. Police said the back door was drilled to gain entrance and the safe was found to be opened. This was the first break-in since the store was opened 12 years ago. On Friday, August 8, two cars crashed through the front window which had to be boarded up.

ASHEVILLE

A man robbed A-B Pharmacy of 500 Dilaudid tablets Wednesday, July 9, 1986, according to Asheville police. The robber, who may have had a weapon, demanded the drug and left the store after making the clerk and a customer lie on the floor.

* * * * *

HOW NOT TO BE A PART OF THE NCPHA (or how to send your association down the tube)

Don't pay your dues promptly . . . they're too high anyway . . . then complain about poor financial management.

Don't encourage others to join . . . that's pushy . . . then complain about stagnation and lack of growth.

Don't volunteer your time and talents . . . that's ego fullfillment . . . then complain about never being asked to help.

Don't read your Association mail . . . it's probably not important . . . then complain about being kept in the dark.

Decline all offices and committee appointments . . . you're too busy . . . then complain about how "they" should do things.

Oppose all social functions . . . they're frivolous and unprofessional . . . then complain about a lack of fun in organizational activities.

If appointed to a committee, don't attend or work . . . it's only a meaningless committee . . . then complain about a lack of new ideas and member input.

And, if by some chance, the association grows in spite of your contributions . . . take every opportunity to tell the younger members how tough it was in the old days, how hard you worked to get the organization to its current level of success.

A PREVIEW OF INDEPENDENT COMMUNITY PHARMACY — 1986

This preliminary *Lilly Digest* report shows that total sales during 1985 increased more than 3% over the prior year but net profit failed to keep pace and declined. Prescription revenue accounted for the overall sales increase, as other sales were down, even though fewer prescriptions were dispensed. Further comparison shows . . .

Total sales established a record high of over $589,000, up more than 3% from the 1984 figure. This is lower than the average annual growth rate of 9% observed over the decade. Interestingly, the average growth rate since 1980 appears to have stabilized in the range of 5 to 6%. Prescription sales rose over 6% and substantially outpaced other sales, which fell 1.6%. Prescription income accounts for more than 66 cents of every revenue dollar.

Gross margin in dollars increased almost 2% but declined to 32.6% as a percent of sales. Total expenses fell to a record low of 29.8% of total revenue. This reduction was the result of a decline in employees' wages, which more than offset an increase in proprietor's salary and in miscellaneous operating costs. The combined effect of these changes was that net profit before taxes fell 7.5% to equal 2.8% of total sales.

Although total expenses declined percentagewise, they increased dollarwise (up about $4,500, or 2.6%, from the previous year). Average proprietor's or manager's salary rose both in dollars (up $1,553) and as a percent of sales (up to 5.9%). Employees' wages declined in dollars and as a percent — down over $500 to 10.1% of sales. Rent advanced almost 6% in dollars but remained unchanged as a percent of sales at 2.4%. Miscellaneous operating costs increased by about $2,700, a 4.2% increase over the previous year's figure. In addition, these costs took up a larger share of the sales dollar — up from 11.2% to 11.4% of total revenue.

Net profit before taxes dropped over 7%, down $1,217 from the 1984 figure. Total income (proprietor's salary plus net profit before taxes) advanced to just over $51,000, a 0.7% rise, but declined as a percentage to 8.7% of sales.

Prescription inventory required a somewhat larger dollar investment (up over $2,400) and increased from 10.5% to 10.6% of prescription income. However, general merchandise inventory required fewer dollars (down almost $500) but rose to 21.9% of general stock sales. The prescription department's sales productivity stayed about the same at $9.47 per stock dollar as compared with $9.50 recorded for 1984. Other merchandise sales productivity also was relatively unchanged at $4.57.

New prescriptions rose as a percent of total prescriptions to 49.5%, but the number of prescriptions dispensed fell slightly as compared with similar figures for 1984. On the average, there were fewer renewed prescriptions dispensed during 1985 — down over 4% from last year. These changes resulted in a 2.4% decline in total prescriptions dispensed. The average prescription charge advanced 8.8% to $13.05 during 1985, an increase of $1.05 over the 1984 figure of $12.00.

The size of the average *Lilly Digest* pharmacy increased 7.4% to over 2,600 square feet during 1985. Sales productivity per square foot of selling space dropped about $7 (down to $222.14) from the earlier year's figure — a 3.3% decline. At 61 hours per week, the typical *Digest* pharmacy was open one hour less during 1985.

The following table summarizes the operating figures of 1,224 independent community pharmacies and compares these with the 1985 *Lilly Digest* database of 1,341 stores. The completed edition of the *Lilly Digest* will be distributed during the fall of this year.

SPECIAL THANKS

Special thanks to Frances Rader Lena, Dallas, Texas, for the two Oriental carpets she donated to the Institute of Pharmacy. Frances, a 1979 graduate of the UNC School of Pharmacy, received her M.S. in Pharmacy Practice in 1982 and has been employed as Director of Professional Affairs for the Texas Pharmaceutical Association until her move from Austin to Dallas. The carpets are both approximately 6½ feet by 10 feet and bring warmth and color to the offices of the Executive Director and the Financial Secretary. Frances and Manuel purchased the carpets on a trip to Morocco in 1985.

Averages per Pharmacy	1985 (Preliminary Sample) (1,224 Pharmacies)	1984 (Full Sample) (1,341 Pharmacies)	Amount/ Percent of Change
Sales			
Prescription	$366,903— 62.3%	$345,435— 60.5%	+$21,468—6.2%
Other	222,439— 37.7%	225,878— 39.5%	-$ 3,439—1.6%
Total	$589,342—100.0%	$571,313—100.0%	+$18,029—3.2%
Cost of goods sold	397,508— 67.4%	382,757— 67.0%	+$14,751—3.9%
Gross margin	$191,834— 32.6%	$188,556— 33.0%	+$ 3,278—1.7%
Expenses			
Proprietor's or manager's salary	$ 34,854— 5.9%	$ 33,301— 5.8%	+$ 1,553—4.7%
Employees' wages	59,598— 10.1%	60,126— 10.5%	-$ 528—0.9%
Rent	14,208— 2.4%	13,428— 2.4%	+$ 780—5.8%
Miscellaneous operating costs	67,016— 11.4%	64,326— 11.2%	+$ 2,690—4.2%
Total expenses	$175,676— 29.8%	$171,181— 29.9%	+$ 4,495—2.6%
Net profit (before taxes)	$ 16,158— 2.8%	$ 17,375— 3.1%	-$ 1,217—7.5%
Total income	$ 51,012— 8.7%	$ 50,676— 8.9%	+$ 336—0.7%
Value of inventory at cost and as a percent of sales			
Prescription	$ 38,753— 10.6%	$ 36,343— 10.5%	+$ 2,410—6.6%
Other	48,625— 21.9%	49,115— 21.7%	-$ 490—1.0%
Total	$ 87,378— 14.8%	$ 85,458— 15.0%	+$ 1,920—2.3%
Annual inventory turnover rate	4.5 times	4.6 times	
Prescriptions dispensed			
New	13,919— 49.5%	13,975— 48.6%	- 56—0.4%
Renewed	14,198— 50.5%	14,801— 51.4%	- 603—4.3%
Total	28,117—100.0%	28,776—100.0%	- 659—2.4%
Average prescription charge	$ 13.05	$ 12.00	+$ 1.05—8.8%
Floor area*	2,653 sq ft	2,471 sq ft	+ 182—7.4%
Sales per square foot*	$222.14	$229.36	-$ 7.22—3.3%
Pharmacy hours open	61	62	- 1—1.6%

*Based on averages of pharmacies that reported all data.

September, 1986

Dickinson's Pharmacy
by Jim Dickinson

Paying and choosing. "He who chooses does not pay, he who pays does not choose." Can you shed a little tear for that old saying about the prescription drug business? It is, after all, going the way of the dodo bird and the dinosaur, to be buried under the weight of "managed health care" in all its modern new forms.

With that old saying will be buried a rich history of medical innovation, new drugs, hardships and enrichments that shaped our lives, and even (some say) the old "corner drug store" and everything it means to us.

While the "chooser" (the prescriber) didn't have to pay for his choices, all was well, more or less.

His choices were seldom *convenient* to pay for, but one way or another, they did get paid for, most of the time — and the system begat the world's highest standard of health care. Nearly all of the great medical advances that you can think of came out of that system, even as we read sometimes of families who were financially ruined right into the next generation by the system's failures.

Now, for at least the past decade, "health care cost-containment" has dominated much of our thinking. While "he who chooses doesn't pay, he who pays doesn't choose" has continued to drive the system, other powerful sets of words have jostled for center stage — "cost containment," "maximum allowable cost," "usual and customary," "the lesser of," "indigent recipient" . . . you know them all.

World crises, oil embargoes, inflation, unemployment, Watergate, liability insurance — all manner of distant events combined to gang up on the trust that fueled the old system. It became too expensive, and the result is "managed care," a euphemism for the new face of cost-containment that is forcing providers to join hands in ways that simultaneously cut waste, reduce costs, and enhance quality of care.

In August, one of the most impressive assessments of this phenomenon to date was unveiled for the medical device/durable medical equipment industry by the Health Industry Manfuacturers Association in Washington. A collaborative endeavor with the prestigious consulting firm of Ernst & Whinney, this assessment measured the strong cost-containment forces at work in health maintenance organizations, preferred provider organizations, hospitals and third party payors.

Its bottom line? Surprise! Quality is more important than price, and little by little, those who pay *and* those who choose are coming to realize it. By the early 1990s, this report said, quality of care will become the central cost-containment mechanism in health.

Hospitals and HMOs will even have MDs making their buying decisions for them, instead of accountants and procurement officers. The "informed consent" doctrine means that the patient is brought in on the decision, and HMOs, PPOs and third-party incentive programs mean that prescribers and beneficiaries alike can share in cost savings. Payors will actually pay more to get quality, realizing that short-term price gains often cost more in the longer term.

You knew it all along. Why is it taking so long for the rest of the health care environment to find out?

One answer is in the same phenomenon that is making life tougher now for discount stores. People are getting older, and they don't care to feel degraded and inconvenienced just to get a cheaper price. When they were younger, they didn't notice being degraded in dirty stores with indifferent sales clerks, or standing in line and having to park two floors down and half a parking lot away. *They were getting a "deal"!*

In health care, degraded by overly competitive practitioners, by costs that soar because of malpractice and liability insurance, by the need to get second opinions, and by epidemic lack of confidence, quality becomes more important than price.

Recognizing this comes slowly. It's hard to get past the cheapest price, and train yourself to look at other factors as well. But experience with mandatory, across-the-board cuts such as "maximum allowable costs," capitation, DRGs, etc., has not provided the panacea that our health planners believe is attainable.

Could it be that the continued escalation in health care costs owes something to the fact that the choosers and the payors have, operating separately, gone for the quick-fix, and have not focused on true, waste-free quality? Yes, that could be, and recognition of that is changing the game.

How to build-in quality, is the question of the

decade. The country's best brains are working on it. The self-discipline of the "managed care" setting, whether hospital, PPO, PSAO, HMO, or whatever, makes it do-able on a grand scale for the first time.

And here is pharmacy, organizing itself in PSAOs and PPOs, waiting with at least some of the answers!

(FREE OFFER: Send a state association mailing label to me at P.O. Box 848, Morgantown, WV 26507-0848, and I will mail you a free copy of my newsletter, Dickinson's PSAQ.)

This feature is presented on a grant from G.D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G.D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G.D. Searle & Co.

Jim Dickinson is president of Ferdic, Inc., a West Virginia corporation and is a widely read correspondent for pharmaceutical and health related publications worldwide. He is a native of Australia where he edited and published the *Australian Journal of Pharmacy* for six years. He was formerly Washington bureau chief for *Drug Topics Magazine* and has served as special consultant to NARD and special assistant to the executive director of APhA. He was managing editor of the *Green Sheet* and senior editor of *The Pink Sheet,* both pharmacy news and pharmacy industry newsletters.

WEDDING

RHONDA DENISE ISLEY and Robert Lewis McIntosh were married Sept. 6, 1986 at Piedmont Presbyterian Church, Burlington, NC. Dr. John E. Eliason and the Rev. Lewis Gibbs officiated.

The bride earned a B.S. in pharmacy from the University of North Carolina at Chapel Hill and is pharmacist/assistant manager at Revco Drug Store, Inc. in Charlotte.

The groom earned a B.S. in computer science for business from DeVry Institute of Technology, Atlanta. He is a systems engineer at Management Science America-The Software Co.

Steve Moore

Steven Richard Moore received his B.S. in Pharmacy in 1970 and his Masters of Public Health in 1978 from the University of North Carolina at Chapel Hill. Currently he is employed by the Food and Drug Administration in Washington, D.C.

Home Health

(Continued from page 15)

articles on the subject. Mr. McAllister is Associate Director of Pharmacy Services, Duke University Medical Center. The book may be ordered from ASHP, 4630 Montgomery Avenue, Bethesda, MD 20814. The stock number is P-239 and the price is $20.00

DEATHS

I. THOMAS REAMER

I.T. "Tom" Reamer, Durham, former chief pharmacist at Duke University Medical Center, died Friday, September 5, 1986. He was 81 years old. Reamer was a graduate of the University of Maryland and was appointed chief pharmacist at Duke University in 1931. He was a charter member of the American Society of Hospital Pharmacists and served as president in 1950–1951. He received the Harvey A.K. Whitney Award, hospital pharmacy's highest honor, in 1959. He was named an honorary member of ASHP in 1977. He was a member of the North Carolina Board of Pharmacy from 1944 to 1947 and was selected as 1967 North Carolina Pharmaceutical Association Pharmacist-of-the-Year.

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CALL FOR PAPERS

The NCSHP Program Committee is calling for papers to be presented in poster format at the Winter Meeting in Charlotte, February 5, 1987. Summaries of papers should be prepared according to the guidelines outlined in the January 1986 issue of *American Journal of Hospital Pharmacy* and submitted to Dennis Williams, Program Committee Chairman, Beard Hall 200H, UNC, Chapel Hill, NC 27514.

The deadline for receipt of papers is December 1, 1986. Notification of acceptance will be sent by December 22, 1986.

Papers submitted for presentation at national meetings are welcome. Please participate and share your work with your North Carolina Colleagues.

A Research Recognition Award, sponsored by the Upjohn Company, will be initiated at this meeting as well. A cash award will be presented for the best paper submitted. Each paper will be Papers submitted for consideration of this award do not necessarily have to be presented at the poster session, but the author should clearly state his(her) intent upon submission.

Thank you!

Mebane

(Continued from page 26)

for *The Pennsylvania Pharmacist* will greatly aid our efforts. Thank you.

Please submit articles to the PPA State Office before January 1, 1987.

Michael P. Hornick, R.Ph., Chairperson
Committee on Crime Prevention Program

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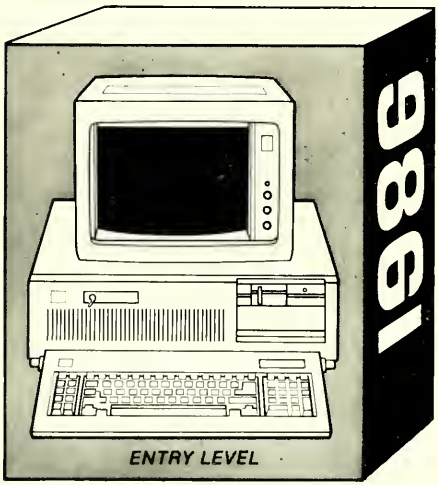

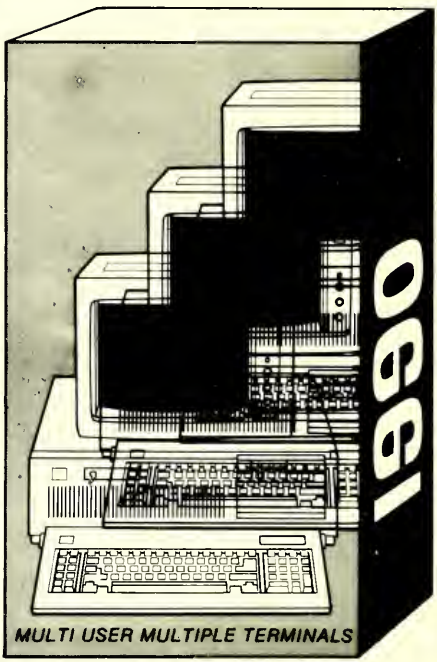

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Photo by Colorcraft

Ronald W. Maddox, Dean, left and Jack G. Watts, Chairman of the Founders Committee, in front of the Campbell University School of Pharmacy following Convocation.

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PHARMACY CONVOCATION HELD

Campbell University School of Pharmacy, the first pharmacy school to open in the nation in 35 years, held its opening ceremonies on Tuesday, September 9, in the Taylor Bott Rogers Fine Arts Center.

Dr. Daniel Nona, executive director of the American Council on Pharmaceutical Education, delivered the keynote address.

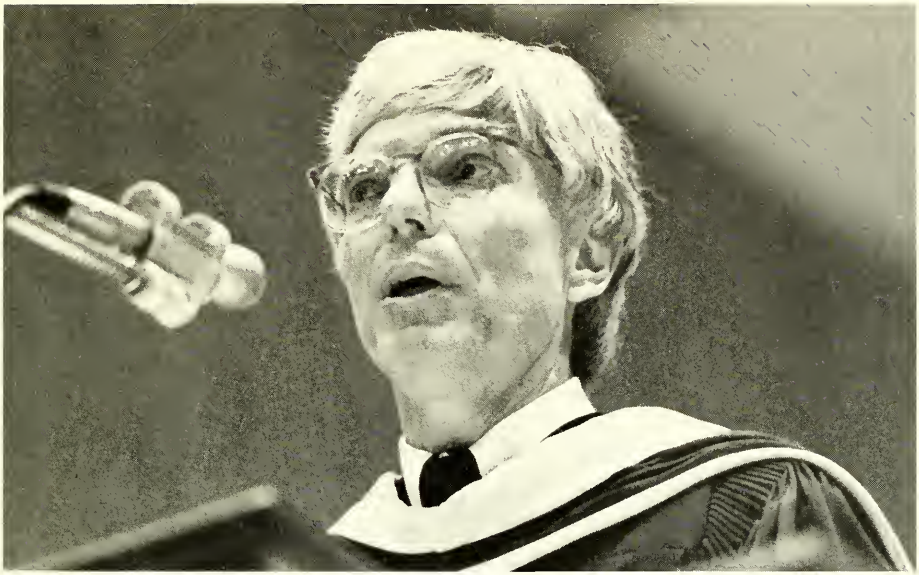
Greetings were given by J. Leon Rumley of Winston-Salem, chairman, Campbell's Board of Trustees; Lewis M. Fetterman Sr., Clinton, chairman, Campbell's Presidential Board of Advisors; Dr. Roy J. Smith, Raleigh, general secretary-treasurer, Baptist State Convention of North Carolina; Dr. H. Garland Hershey, Chapel Hill, vice-chancellor, Health Affairs, University of North Carolina-Chapel Hill; Dr. Tom S. Miya, Chapel Hill, School of Pharmacy, University of North Carolina-Chapel Hill; M. Keith Fearing Jr., Manteo, president, North Carolina, president, North Carolina Pharmaceutical Association; Steve Dedrick, Durham, president, North Carolina Society of Hospital Pharmacists; William Randall, Lillington, North Carolina Board of Pharmacy; and Dr. Jerry Wallace, Buies Creek, vice-president for Academic Affairs, Campbell University.

Dr. Oliver M. Littlejohn, vice-president of Mercer University in Georgia and Campbell's consultant in the establishment of the School of Pharmacy, recognized special guests.

Dr. Norman A. Wiggins, president of Campbell, spoke of the Campbell University perspective of the new pharmacy school. "We are grateful for the privilege of preparing young men and women for the important and serious responsibilities that they must discharge as pharmacists. Campbell University School of Pharmacy will take as its primary purpose to help young people who come for an education to understand that making a life is more important than making a living," Wiggins added.

In his keynote address, Dr. Nona spoke of the establishment of the first pharmacy school in 1820 and of the crude use of drugs, "which mostly aggravated instead of alleviating diseases and sickness. While Campbell University School of Pharmacy, our nation's newest school, will carry on with responsibilities and teaching,

Participating in Campbell's Pharmacy Convocation were: (l. to r.) Dr. Norman A. Wiggins, president of Campbell University; Dr. Ronald Maddox, dean of Campbell's Pharmacy School; Dr. Daniel Nona, keynote speaker for the Pharmacy Convocation; and J. Leon Rumley, chairman of Campbell's Board of trustees.



Dr. Daniel Nona delivers the convocation address in the Campbell University Pharmacy School opening ceremonies on Tuesday. (Photo by Todd Scarborough)

research and public service, the school is born on a new societal landscape. The School of Pharmacy opens upon the cusp of profound changes in health care delivery, and it faces educational and professional challenges which are associated with these changes," Nona said.

Nona discussed the changes in health care services, including health care financing, Health Maintenance Organizations, hospital stays, and the loss of the traditional medical students' and residents' observations.

"People in our society are accepting responsibility for their health through nutrition-consciousness, exercise, stress-management, promotion of responsible drinking habits, non-smoking and drug awareness, pharmacy practitioners have the responsibility to promote and respond to this trend," Nona said.

In closing, Nona delivered convocation charges to the university, School of Pharmacy administration, faculty and students. "This school of pharmacy, as with the first school of pharmacy, should benefit the university, profession and society. On behalf of the profession, I welcome you all to the community of pharmacy and extend to you every good wish."

A luncheon followed the ceremonies and was sponsored by the Burroughs Wellcome Company.

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Front left to right:
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CORRESPONDENCE COURSE

WARTS AND THEIR TREATMENT

by Thomas A. Gossel, R.Ph., Ph.D.
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Goals

The goals of this lesson are to:
1. discuss the etiology and treatment of warts;
2. review the pharmacology and therapeutics of OTC and prescription remedies for warts.

Objectives

At the completion of this lesson, the successful participant will be able to:
1. choose the appropriate OTC and prescription agents for treating warts;
2. explain the proper technique for applying these OTC and prescription agents.

Introduction

In this month's lesson, we bring the good news that kissing a toad will not cause warts. Likewise, rubbing warts with a stolen dishrag at midnight under a full moon is not a cure! Warts have fascinated mankind for many years and have been the subject of volumes of publications speculating on their causes and treatment. Their role in providing a form of visual punishment to the bearer of some ill-done deed is well documented in folklore. Even the medical literature, through the first quarter of this century, declared that little was known about warts and that their treatment was, at best, symptomatic.

Today, we know that viruses cause warts. We also know how to approach treating them. Treatment is not always totally complete, but various methods are at least directed toward the correct cause — viruses.

This month's lesson reviews the etiology, characteristics, and treatment of warts. Most importantly, it discusses specific patient advice a pharmacist should convey to consumers who wish to self-treat warts.

Etiology of Warts

Warts are benign papillomas (noncancerous elevations). They are caused by epidermotropic DNA human papovavirus (HPV). This means they only affect the epidermal layers of skin and do not invade the deeper layers, and that they take over the DNA synthesis mechanisms in human cells and cause them to manufacture these substances for their own reproduction.

At least eight strains of wart-causing viruses have been positively identified, but it is speculated there are several other strains that will be distinguished in the future. HPV is specific to human cells and has not yet been isolated from nonhuman tissue. Thus, attempts to grow it *in vitro* in non-human tissue cultures for purposes of study have not yet been successful. This has been the greatest handicap thus far in assessing why we are still deficient in important information about warts.

HPV viruses are also specific as to the types of

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Correspondence Course

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warts they cause. For example, HPV 2 causes most common warts. HPV 3 is the source of plane warts. HPV 2 and HPV 6 are the factors involved in most anogenital wart formation. Other warts may be caused by a combination of these viruses. It is not known just how the various HPV strains relate, if at all, to specific areas on the body, or to the appearance and clinical outcomes of warts.

Warts, as with most other viral infections, are contagious. They can appear on adjacent fingers or toes or can be transmitted to other people either through contact, or by indirect means such as public showers and swimming pools.

The incubation period for warts varies from one to twenty months; the average time is three to four months. They may occur on any area, although they are most common on pressure points, areas of scratching, and other sites of irritation. Trauma is thought to be one of the etiological factors that stimulate the wart-causing viruses to begin their activity.

Persons of all ages may get warts. They are most common in the teenage years, and rare in babies and very young children. It is reported that 10 percent of all teenagers have warts. More than 20 percent of the population may be continually bothered by them. Almost everyone will have one or more warts sometime during his lifetime.

Persons of all cultures representing all countries of the world get warts. They occur more commonly in persons engaged in certain occupations. For example, individuals such as butchers or fish handlers who work around moist areas are at high risk for developing warts on their hands and arms. Furthermore, persons with certain immunological deficiencies such as those encountered in Hodgkins's disease, and those individuals on chronic immunosuppressant

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therapy have a greater incidence of wart development. They also respond poorly to drug treatment.

Warts may increase in size during pregnancy, and genital warts are more common during the active sexual years.

Types of Warts

Common Warts (*verrucae vulgaris*). Common warts are the most frequently seen warts. They are predominant on the hands and around the nail beds, but can appear anywhere on the body. They sometimes emerge around the genitalia, but should not be confused with genital warts. Most measure 1 mm to 2 mm in diameter, are rounded or irregular in shape, and have a rough surface.

Common warts are light grey to yellow-brown in color, occasionally appearing grayish-black. When they darken, it usually means that tiny blood clots are underneath the surface. These warts will bleed on removal. Common warts usually occur in multiples, although single warts are frequently seen in older people.

Periungual Warts. A periungual wart refers to those found specifically around the nail plate. They are frequently associated with nail biting. They are also usually resistant to treatment. When severe, periungual warts may increase in size sufficiently to cause the nail plate to actually separate from the finger.

Plantar Warts (*verrucae plantaris*). Plantar warts are occasionally mistaken for corns or calluses. They appear on the plantar (bottom) surface of the feet. Plantar warts are round and rough, and may be soft or firm. They do not protrude above the skin's surface. Most people have only one plantar wart at a time. When several plantar warts are aligned together, they are termed mosaic warts. Plantar warts can be distinguished from corns and calluses by pressing on their outer edges with a knife blade. Plantar warts have a soft inner core. Corns and calluses have a hardened inner area. Plantar warts frequently turn black and become painful just before their normal resolution.

Plane Warts (*verrucae planae*). Plane warts, also called flat warts, commonly appear on the forearms, backs of the hands, the face, and the knees. They are small, rarely exceeding 1 to 5 mm in diameter. They appear as flat or slightly elevated lesions that are slightly off-color and may be readily mistaken for a rash. Plane warts may redden and begin to itch with even greater intensity just before disappearing.

Anogenital Warts. (*condyloma acuminata*). Anogenital warts are those that appear on the anorectal area or genitalia. They appear as a cauliflower-like structure, often measuring 2 to 3 cm in diameter. They are soft, pink, and usually confined to external areas, although they may occur within the vagina or anus. Anogenital warts are extremely painful and are readily contagious. They are usually spread by sexual contact.

Digitate (filiform) Warts. These appear as long and thin thread-like structures. They are usually seen on the face around the nose and mouth. They are most common in boys and young men.

Treatment

Most warts disappear spontaneously, months to years after they appear. Warts in multiples may disappear one at a time or all at once. In one survey of more than 1,000 children who had warts, 54% of them noted that the warts disappeared within a year of first being noticed. Sixty-seven percent experienced disappearance of their warts within two years.

Warts do not disappear over night, contrary to what some people believe. When an individual reports that such quick resolution did occur, it is just that the person has failed to notice the slow process over the previous several weeks, months, or years.

Warts seldom return at the same location. However, on occasion they do. When this occurs, the individual's immunity that developed against the warts was probably not complete. Conversely, the new wart may be caused by a different strain of HPV.

Immunological Defense. The body's immunological system is responsible for warts disappearing. The body forms a localized cell-mediated defense mechanism rather than a generalized reaction as it does with systemic bacterial infections. Thus, circulating antibodies are not found when warts have disappeared.

Warts seldom require medical treatment because they heal spontaneously. However,

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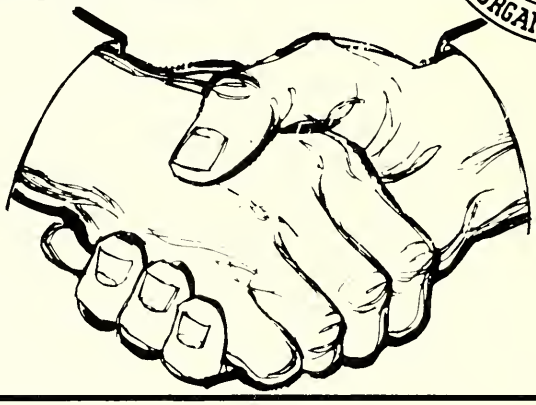

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Correspondence Course

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when they impair normal functions, are cosmetically unacceptable (e.g., on the face), or are extremely painful, they should be removed. Only a physician should attempt to remove warts on the face or anogenital area.

Avoidance of scarring and permanent damage to surrounding tissue should be the primary goal of therapy. If scars form on a weight bearing surface, they can cause a lifetime of pain and discomfort. If this goal must be compromised, no treatment should be undertaken.

The treatment of warts is dependent upon establishment of immunity, and no treatment will be effective until this occurs. Some treatments provide palliative relief of symptoms and are, therefore, logical. However, most treatments may be viewed as "buying time" until the body's natural immunity is established. Many attempts have been made to correct this immune deficiency or to alter individual responses. However, none have thus far been successful.

The absolute "cure" for warts occurs when the affected person develops a natural immunity. Many studies have shown that the peak concentration of virus in most warts occurs when the warts are about six-months-old. The body may require another six to twelve months to produce sufficient antibodies to combat these viruses. Topical therapy will not help stimulate formation of these antibodies, and some authorities have cautioned that premature destruction of a wart may enhance reinfection. Thus, there are strong arguments for leaving a wart alone, at least until this immunity has occurred (at least six to twelve months after the appearance of the wart).

The FDA advisory panel that reviewed OTC wart removers suggested that common warts and mild plantar warts can be self-treated with OTC medication.

OTC Wart-Removers. The above mentioned advisory panel has recommended that salicylic acid (in concentrations of 5 to 17% in flexible collodion) should be classified as a Category I agent (i.e., safe and effective) for removing warts. No other substance was so designated. Other ingredients of OTC products evaluated by the panel are listed in Table 1.

TABLE 1
Wart Remover Ingredient Classification*

Classification	Ingredient(s)
Safe and effective (Category I)	Salicylic Acid
Either unsafe or ineffective (Category II)	Benzocaine Camphor Castor Oil Iodine Menthol
Needs more study to prove effectiveness (Category III)	Acetic Acid Ascorbic Acid Calcium Pantothenate Lactic Acid

*as recommended by an FDA advisory panel.

Salicylic Acid. Salicylic acid is a keratolytic (peeling) agent which softens and destroys cells in the outer layer of skin. This action is thought to result from increasing endogenous hydration of the tissue, most likely by lowering its pH. By causing a dissolution of the skin's intracellular cement substance, keratin becomes swollen, softens, and sheds.

The advisory panel made special note about collodion and its component, the nitrocellulose derivative, pyroxylin, as a vehicle for salicylic acid. Recall that pyroxylin contains the volatile solvents ether and alcohol and the plasticizers camphor and castor oil. Applied to a wart, the solvents volatilize leaving behind a layer of pyroxylin as the insoluble water repellent film. This ensures a close contact between the medication and wart, and therefore, complete absorption of the active drug into the affected tissue. Because of the nature of its rigid film, accidental drug loss due to run off onto surrounding tissue is minimized.

Category II Ingredients. Benzocaine, camphor, castor oil, iodine and menthol were all listed as Category II because they lacked data demonstrating either safety or effectiveness when used in OTC wart remover products. However, several of them may be retained as "inactive" ingredients.

Category III Ingredients. Included as Category III ingredients were acetic acid, ascorbic acid, calcium pantothenate, and lactic acid. The advisory panel indicated that each of these agents required more study before the agent

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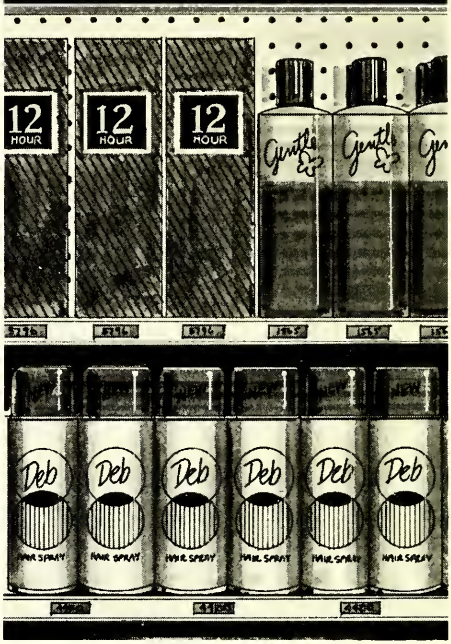

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could be listed as effective. They are all safe, but they cannot be proven effective OTC wart remover ingredients.

Lactic acid is of special interest. This has long been used in wart remover products and is currently employed in numerous formulations in 2 to 10% concentrations. The substance has not been demonstrated to be an active keratolytic agent alone, but there is some evidence that it indirectly influences the keratinization process. Furthermore, all current data that discuss lactic acid as a keratolytic for wart removal were obtained from studies in which it was combined with salicylic acid. The advisory panel recommended that specific studies are needed to clarify the effectiveness of lactic acid used alone.

Manufacturers of products that contain Category III ingredients are currently in the process of gathering data to establish effectiveness of these ingredients. Meanwhile, products containing Category III ingredients can continue to be marketed until FDA formally acts on the panel's report.

Prescription Drugs

Several agents that require a prescription are included to complete this discussion.

Cantharidin ("spanish fly") is a potent keratolytic that induces epidermal cell separation and destroys the wart. It will also cause similar damage to healthy tissue. Therefore, most physicians prefer to apply it themselves rather than prescribe it for self-treatment by the patient.

Currently, it is prepared as a 0.7% solution in equal parts of flexible collodion and acetone. A few drops are placed on the wart and covered with non-porous tape. The patient is advised to remove this tape after a day or so and replace it with a loose bandage until the next office visit, usually a week later. One treatment is normally sufficient. However, some will need a second application.

While pain is not noted immediately following its application, cantharidin does cause mild to moderate pain 12 or so hours later in up to 50% of individuals treated. In the event that this occurs, patients should be advised to take OTC analgesics as needed.

Mono-, di-, and trichloroacetic acids are generally reserved for large, recalcitrant warts that appear on the feet and anal areas. These acids are extremely caustic and require subsequent applications. Therefore, some physicians will prescribe them for the patient to apply at home.

Patients using a medication that contains one of these acids should be advised to cover the surrounding tissue with petroleum jelly before applying the acid. Any normal tissue that comes in contact with the product should be immediately and thoroughly washed with soap. Applying a slurry of sodium bicarbonate following this procedure will help neutrallize any remaining acid.

Podophyllin (usually prepared in tincture of benzoin) has been shown to be useful for warts in moist areas. It should be used with caution on genital and anal warts, but many authorities rate it as the agent of choice for warts in these areas. Suggested therapy consists of applying the product, leaving it on for about 14 hours, washing the area, and then applying more medication. This may be repeated as often as needed.

Additionally, other treatments requiring physician supervision include acyclovir, retinoic acid, idoxuridine, methotrexate, formaldehyde or glutaraldehyde, and fluorouracil. Appropriate advice for each of these agents should be passed on to the patient.

Formerly, x-rays were used to treat warts. Today, most authorities generally agree that the risks of excessive radiation exposure far outweigh potential benefits. Warts can also be cut off, burned off, or frozen with liquid nitrogen or dry ice.

Consumer Advice

It is important that consumers purchasing wart removal products understand that warts which are self-treatable will generally disappear spontaneously even without treatment. Anal, genital, and plane warts, as well as any wart on the face should not be self-treated with OTC products. Diabetics and others with chronic diseases of the circulation should not attempt to self-treat their warts.

When a wart remover is desired, the individual should be advised that compliance is mandatory, that the medication must be applied exactly as directed, and that a dermatologist or podiatrist should be consulted if no improvement is noted after a month or so of therapy. If excessive irritation occurs, the medication should be immediately discontinued. Commercially available products at the time of preparation of this lesson are listed in Table 2.

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TABLE 2
Representative OTC Wart Remedies

Product	Dosage Form	Salicylic Acid Concentration (%)	Other Ingredients*
Calicylic	Cream	10	—
Compound W	Liquid	14.2	acetic acid
Off-Ezy	Liquid	17	—
Vergo	Cream	—	ascorbic acid and calcium pantothenate
Veruka-10	Liquid	10	lactic acid
Wart-aid	Cream	—	ascorbic acid and calcium pantothenate
Wart-Off	Liquid	17	—

*effectiveness will need to be proven for manufacturers to continue to claim these ingredients as active.

Warts that are larger than 1 cm in diameter, occur in multiples, or are involved with inflammation should not be self-medicated. Rapidly growing warts, those discharging fluid or blood, and those that have failed to respond to previous treatment should likewise not be self-medicated. All of these require diagnosis and treatment by specialists who fully understand the proper therapy of warts.

In any instance, proper hygiene is essential since warts are contagious. The hands should be washed well before and after treating warts, and separate washcloths and towels should be used. If the wart is on the sole of the foot, it is unwise to walk around barefooted.

Additional advice for patients contemplating purchase of an OTC wart remover product is listed in Table 3.

TABLE 3
Patient Advice

- Since treatment may take six weeks or longer, compliance with therapy is extremely important.
- Apply the medication exactly as directed.
- Do not cut, scrape with a sharp instrument, or scratch deeply into the wart area.
- Wash hands before and after treating a wart.
- If a wart shows no improvement after 12 weeks of treatment, see your doctor.
- Discontinue use of this medication if excessive irritation occurs.
- Do not apply a wart remover product to moles, birthmarks, or unusual looking warts with hair growing from them.
- Apply petroleum jelly around the wart to protect surrounding tissue from accidental application of the wart remedy.
- If the wart is being treated or appears injured, use a separate towel and wash cloth for cleansing the wart area.
- When warts are present on the feet, do not walk barefooted.
- *For solutions:* Apply one drop at a time. Wait for it to dissipate over the wart, then apply another drop if necessary. This minimizes spread (contamination) of the surrounding skin. Keep out of reach of children.

Please turn to Correspondence Course Quiz on Page 32

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LOCAL NEWS

Wilkesboro

An armed robber held up Super X Drugs on Monday, August 11, 1986 and demanded Dilaudid, Demerol, Percodan and Ritalin. He held a paper bag which he gave to the pharmacist to "fill up." The robber was about 25 to 30 years old, 5 feet 10 inches tall.

Hickory

Peoples Drug Store, Startown Plaza, was held up by an armed bandit in his mid 20's, on Saturday, August 2, 1986. The robber threatened the pharmacist who supplied Demerol and Percodan and then was made to lie on the floor while the robber left. Other employees and customers were unaware of the crime taking place.

Dobson

Two men tried to rob Rite-Aid with knives as weapons but were thwarted in the attempt by a quick thinking customer who left and called the sherriff. Officers arrived in time to arrest the two in the store. The robbery attempt took place on Monday night, August 18, 1986 about 7:00 pm. The two men admitted they were planning to rob an Eckerd's store in town earlier but were "scared off."

Lenoir

A burglary at Gamewell Drug is being investigated by Lenoir Police. A large rock was thrown through the front glass door about 1:30 am and drugs and syringes were taken. The robbery occurred Monday morning, September 1, 1986.

Bryson City

Bennett's Drug Store was the scene of breaking and entering early Monday morning, September 8, 1986. A substantial quantity of controlled substances, mostly Valium, was taken.

PHARMACY MEMORABELIA SOUGHT

The North Carolina Museum of History in Raleigh is planning for a new building to be completed in about four years which will triple its existing exhibit area. NCPhA President M. Keith Fearing Jr. has appointed a committee headed by Mr. W.J. Smith, former Executive Director of the NCPhA, to develop a permanent pharmacy exhibit in the new facility.

The committee has met with museum personnel and dialogue is continuing, with the desired circa 1925 pharmacy display contingent upon donation of sufficient authentic pieces to develop a meaningful and accurate pharmacy.

The project is in three stages: Planning the exhibit and solicitation of needed inventory and equipment; Installation of the pharmacy; and dedication of the pharmacy. Items must be contributed, as this is a permanent display. This is a project all pharmacists should be proud to assist. If you have items such as might have been used in a pharmacy sixty years ago, such as patient medicines and cosmetic, reference books, balances and weights, wrapping counter or cash register, wrapping string dispenser, back bar for a fountain or any similar fountain equipment, postage stamp dispenser or penny scales, display cases or wire-back chairs and tables for fountain use, contact W.J. Smith at 908 Arrowhead Road, Chapel Hill, NC 27514. Do not send the items yet! You may wish to include a Polaroid picture of the item with your description to help Mr. Smith and the committee.

This is an opportunity that must not be wasted. Every item that is precious to you as part of your pharmacy heritage will be even more so in the Pharmacy Exhibit of the Museum of History.

BIRTHS

DEBBIE RITTER HOUSTON (Class of 1978) and husand, John, announce the birth of their first child, Bradford Tyler, on April 25, 1986. Debbie practices pharmacy at Humana Hospital in Greensboro.

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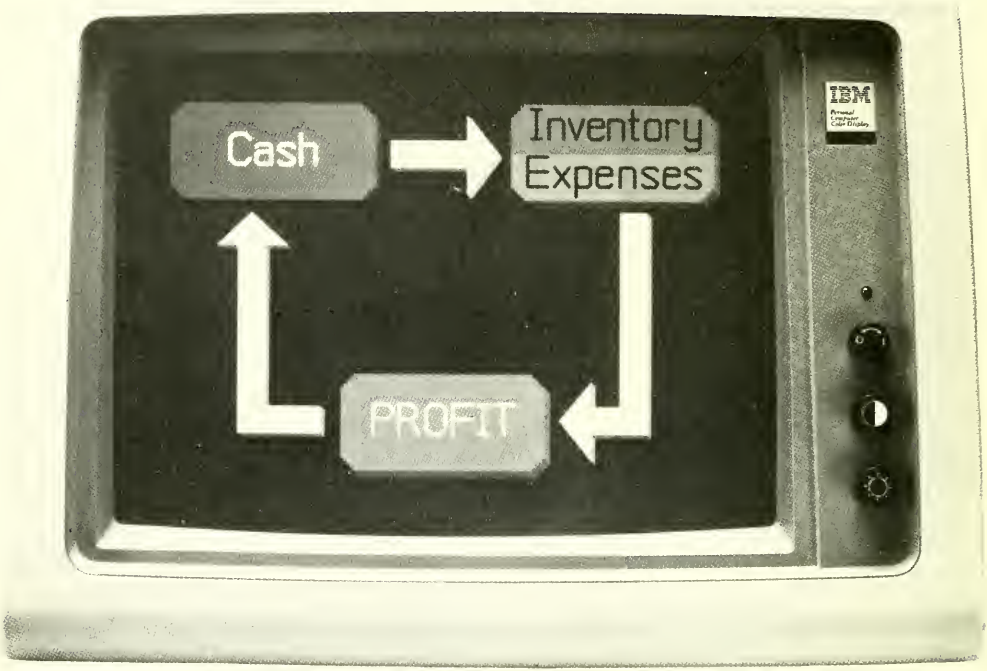

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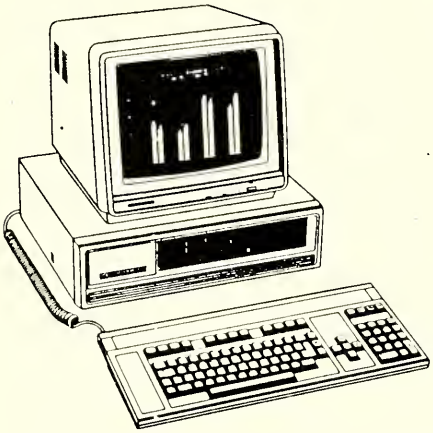

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DICKINSON'S PHARMACY

by Jim Dickinson

Disparagement of generics. "Too soon, old. Too old, smart" — haven't you always wondered why discomforting situations are so predictable after they've happened?

When our lawmakers make the same kinds of mistakes we do, we know we have a democracy, with all its human-scale flaws. And, it seems, this is exactly what's happened on the generic drugs front, after the Waxman-Hatch law that was supposed to increase the number of new generics while granting longer market exclusivities to innovator drugs.

It has done the former just as it intended, but there are troubles with the latter, and that's bringing all kinds of hassles into the pharmacy.

If our lawmakers hadn't been so naive, they might have predicted that innovator companies — who didn't want *any* new generics at all, to begin with — would expect, and take, substantial compensation if they could be persuaded to go along with the bill. Congress thought they'd be satisfied with patent extension, without realizing that was only a "tomorrow" benefit vs. the generics' "today" gains at the expense of some key products by firms lacking early blockbusters in their research pipeline.

Like some of us, corporations sometimes jump to the closest bottom line, the first quick-fix.

The way some brand heavyweights have reacted is a rerun of the 1976 MAC/EAC program dogfights — pure disparagement of generic drug quality and bioequivalence, even when it's FDA-assured. (Psst! did you know that FDA lies when it gives out bioequivalence ratings? Psst! did you know that XYZ Co.'s latest drugs don't have full approval? Psst! did you know All-American Insurance isn't covering generics any more? Psst . . .)

The most interesting situation, though, is "the legal threat" of generics. Psst! did you know you could go to jail like that pharmacist in Ohio if you substitute these new generics?

Some facts may be in order. It should be remembered how much pressure Congress was put under when the Waxman-Hatch generic legislation was finally passed back in 1984. The PMA firms split into opposing camps, and the generics did, too. How could all the competing interests be balanced? Loaded guns were put against heads. It wasn't the kind of climate for careful, measured considerations. In the end, the law was imposed by Congressional compromise upon the industry, and the generics got more out of it than the brands.

As a result, some of the brand name firms today feel that they got a raw deal, and they mightn't be above stealing what they feel was paid for but not delivered.

One of those situations is where, in the last-minute scramble to compromise or lose the whole ballgame, certain innovators were granted label exclusivity for new indications they researched just before their patents expired. It would be unfair, they had said, to let FDA give easy approvals to generics for those new indications that cost us so much to get. That would be a free ride.

Agreed, said Congress. So today we have situations where some therapeutically identical products have unequal labeling, and the brand name innovator would have you believe it's illegal to substitute the generic for his product, or your insurance won't cover you if you do.

Congressman Henry A. Waxman, who did probably more than anyone else on Capitol Hill to bring the new drug law into being, thinks this is nonsense, as do most other experts.

There's no case law in this area yet — and there probably won't be, because the bottom line is that the pharmacist is not responsible if he obeys applicable state (Rx, formulary) and federal (drug approval) laws. What the prescriber was *thinking* isn't the pharmacist's legal responsibility, so long as the correct, bioequivalent drug entity is dispensed to the correct patient according to law.

Is it *moral* to substitute a one-indication generic for a two-indication innovator under the new law? A better question might be, was it *smart* for Mr. Waxman, et al, to attempt to give innovators such an unworkable deal?

In these enlightened days of mandatory substitution, formularies, and cheapest-is-best, it's hard to think what else Congress could have done. On one hand, they had innovators saying "We won't invent new indications if we don't have an incentive," and on the other, they had generic interests and consumer groups saying, "A single new indication, however good, shouldn't deprive patients of an economical generic for a drug that's had the market to itself for 22 years."

I'm not wise enough to know the answer to

(Continued on page 35)

NORTHEASTERN CAROLINA PHARMACEUTICAL SOCIETY

The fifth meeting of the Northeastern Carolina Pharmaceutical Society met on Wednesday, October 15, 1986 at Cobb's Restaurant at the Holiday Inn in Williamston.

Mr. Ken McArthur of Smith, Kline and French Pharmaceuticals sponsored our program. Our speaker was Charles Wayne Wert Pharm D., Director of Pharmacy Education in Family Medicine at Medical University of South Carolina. His topic was "Update of the Treatment and Management of Rheumatoid Arthritis".

There were 32 members present. Special guests included Mitch Miller, Scott Plylar, Amy West and Liz McDonald, fifth year pharmacy students; Ken McArthur and Charles Wayne Wert Pharm. D.

We would like to extend a special thanks to Smith, Kline and French for sponsoring our program. This program provided 1.0 hour of CE credit.

Our next meeting will be our Christmas party on December 7 at the Holiday Inn in Williamston.

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LILLY DIGEST AVERAGES OF SELECTED OPERATING STATISTICS

AVERAGES PER PHARMACY	1985 NORTH CAROLINA (45 Pharmacies)	1985 SOUTH ATLANTIC REGION (205 Pharmacies)	1985 Average UNITED STATES (1,378 Pharmacies)
SALES			
Prescription	$449,641— 69.6%	$366,345— 61.1%	$369,595— 62.2%
Other	196,484— 30.4%	188,064— 33.9%	224,323— 37.8%
Total Sales	$646,125—100.0%	$554,409—100.0%	$593,918—100.0%
COST OF GOODS SOLD	427,380— 66.1%	370,041— 66.7%	400,255— 67.4%
GROSS MARGIN	$218,745— 33.9%	$184,368— 33.3%	193,663— 32.6%
EXPENSES			
Proprietor's or Manager's Salary	$ 39,309— 6.1%	$ 35,977— 6.5%	$ 35,196— 5.9%
Employees' Wages	68,739— 10.6%	56,818— 10.2%	60,316— 10.2%
Rent	14,634— 2.3%	12,182— 2.2%	14,166— 2.4%
Miscellaneous Operating Expenses	65,716— 10.2%	59,850— 10.9%	67,422— 11.3%
Total Expenses	$188,398— 29.2%	$164,827— 29.8%	$177,100— 29.8%
NET PROFIT (before taxes)	$ 30,347— 4.7%	$ 19,541— 3.5%	$ 16,563— 2.8%
Add proprietor's withdrawal	39,309— 6.1%	35,977— 6.5%	35,196— 5.9%
TOTAL INCOME OF SELF-EMPLOYED PROPRIETOR (before taxes on income and profit)	$ 69,656— 10.8%	$ 55,518— 10.0%	$ 51,759— 8.7%
VALUE OF INVENTORY AT COST AND AS A PERCENT OF SALES			
Prescription	$ 42,848— 10.2%	$ 38,810— 10.6%	$ 38,939— 10.5%
Other	41,524— 21.1%	38,795— 20.6%	49,375— 22.0%
Total Inventory	$ 87,372— 13.5%	$ 77,605— 14.0%	$ 88,314— 14.9%
ANNUAL RATE OF TURNOVER OF INVENTORY	4.9 times	4.8 times	4.6 times
FLOOR AREA*	2,735 sq. ft.	2,573 sq. ft.	2,672 sq. ft.
SALES PER SQUARE FOOT*	$ 236.25	$ 215.83	$ 219.98
RENT PER SQUARE FOOT*	$ 5.35	$ 4.73	$ 5.30
NUMBER OF PRESCRIPTIONS DISPENSED			
New	16,053— 45.1%	14,243— 48.5%	14,086— 49.7%
Renewed	19,518— 54.9%	15,139— 51.5%	14,261— 50.3%
Total Prescriptions	35,571—100.0%	29,382—100.0%	28,347—100.0%
PRESCRIPTION CHARGE	$ 12.64	$ 12.47	$ 13.04
NUMBER OF HOURS PER WEEK			
Pharmacy was open	63 hours	61 hours	62 hours
Worked by proprietor	47 hours	50 hours	49 hours
Worked by employed pharmacist(s)	44 hours	37 hours	36 hours

*Based on averages of pharmacies that reported all data.
**Source: 1986 *Lilly Digest*

CORRESPONDENCE COURSE QUIZ

Warts

1. The type of wart that is most commonly mistaken for corns or calluses is the:
   a. common wart.
   b. digitate wart.
   c. periungual wart.
   d. plantar wart.
2. As a rule, the best cure for most warts is:
   a. an antiviral agent.
   b. natural immunity.
   c. surgical removal.
   d. a topical keratolytic.
3. The chemical name for the keratolytic agent found in "Spanish Fly" is:
   a. cantharidin.
   b. lactic acid.
   c. podophyllin.
   d. trichloroacetic acid.
4. A consumer requesting a wart remover containing the highest strength of salicylic acid should be advised of which of the following products?
   a. Calicylic or Compound W
   b. Off-Ezy or Wart Off
   c. Scholl's Wart Remover or Wart-aid
   d. Vergo or Veruka
5. All of the following statements about warts are true with the EXCEPTION of:
   a. They are contagious to other parts of the body and to other persons.
   b. They are self-limiting and usually disappear spontaneously with or without treatment.
   c. They spread from the epidermal areas to deeper layers of the skin if not treated properly.
   d. The invading viruses are specific to human cells and have not yet been isolated from nonhuman tissue.
6. All of the following activities are associated with the wart removal action of salicylic acid EXCEPT:
   a. antiviral activity or the infective organism.
   b. dissolution of the skin's intracellular cement.
   c. increased endogenous hydration of skin.
   d. lowering the pH of the skin.
7. The FDA advisory panel for wart removers placed all of the following in the "needs more study" category with the EXCEPTION of:
   a. ascorbic acid.
   b. benzocaine.
   c. calcium pantothenate.
   d. lactic acid.
8. The advice to avoid walking barefooted is most appropriate for individuals who have which of the following types of warts?
   a. Common warts.
   b. Digitate warts.
   c. Periungual warts.
   d. Plantar warts.
9. The type of virus that causes warts is the:
   a. adenovirus.
   b. herpesvirus.
   c. papovavirus.
   d. toadavirus.
10. A person who has a condition called *condyloma acuminata* has:
    a. anogenital warts.
    b. common warts.
    c. periungual warts.
    d. plantar warts.
11. The agent that is prescribed in tincture of benzoin for application to warts and is especially useful in those growing in moist areas is:
    a. cantharidin.
    b. lactic acid.
    c. podophyllin.
    d. trichloroacetic acid.
12. A potent keratolytic that most physicians prefer to apply themselves is:
    a. podophyllin.
    b. trichloroacetic acid.
    c. cantharidin.
    d. lactic acid.
13. Periungual warts are most commonly found:
    a. around the anal area.
    b. around the nail plate.
    c. on the face.
    d. on the sole of the foot.
14. All of the following substances are components of flexible collodion EXCEPT:
    a. acetic acid.
    b. camphor.
    c. castor oil.
    d. ether.
15. Which of the following statements is true?
    a. Warts most frequently reappear at the same location.
    b. Persons with warts are affected by only one of the various types of viruses, but not the others.
    c. When warts disappear, it is spontaneous, usually occurring overnight.

d. Viruses that cause warts do so by invading epidermal cells and taking over their DNA synthesis mechanisms.

EVELYN LLOYD HONORED BY COUNTY COMMISSIONERS, BOARD OF HEALTH

Evelyn P. Lloyd of Hillsborough, North Carolina was recently honored for nine years of service as a Member of the Orange County Board of Health in North Carolina. She was cited for her outstanding dedicated service and leading the Board of Health as its Chairman from 1981 to 1986.

In an unusual action the Orange County Commissioners recognized Evelyn for her dedication and compassion while demonstrating a keen insight into the concerns of Orange County citizens. The Commissioners also commended Evelyn for her faithful service and leadership. Evelyn has also served as a Member of the Executive Committee of the North Carolina Pharmaceutical Association and began her second term this year as a Member of the North Carolina Board of Pharmacy.

Evelyn Floyd

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Warts

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1. a b c d	*4. a b c d*	*7. a b c d*	*10. a b c d*	*13. a b c d*
2. a b c d	*5. a b c d*	*8. a b c d*	*11. a b c d*	*14. a b c d*
3. a b c d	*6. a b c d*	*9. a b c d*	*12. a b c d*	*15. a b c d*

Evaluation ☐ Excellent ☐ Good ☐ Fair ☐ Poor

How long did it take you to read the article and complete the exam? _____

FOODS FOR HEALTH

Noted nutritionist Jane Brody has identified the 10 best foods for good health. They are:

Broccoli and carrots. These, like most dark green and deep red vegetables, are low in calories and high in vitamin A and fiber. They are also purported to contain a natural cancer-preventive agent.

Oats. Oats are a rich source of protein and fiber. Cooked oatmeal is more nutritious than instant, and adding skim milk provides protein and calcium.

Cabbage. The entire cabbage family (including cauliflower, Brussels sprouts, and kale), according to Brody, reduces the chances of colon cancer.

Potatoes. Potatoes are an excellent source of vitamin C, protein, iron, riboflavin, thiamine, niacin, phosphorus, and magnesium — with fewer than 100 calories per five-ounces. Avoid the added sour cream and butter. Substitute yogurt flavored with dill, pepper, or horseradish.

Yogurt and skim milk. Both are high in calcium without high fat content. Versatile yogurt can be added to a variety of fruits, vegetables, soups, dips, salads, and desserts.

Pasta. Without heavy sauces, pasta is not especially fattening, and is high in protein, vitamins, and minerals.

Fish. Not only high in protein, many types of fish contain oils that lower blood cholesterol levels.

Whole grain breads. Not all brown breads are necessarily whole grain. The first ingredient listed on the package should be a whole grain (oats, whole wheat, etc.)

Lentils. Lentils (as well as other dried beans and peas) are high in protein and fiber, and according to Brody, help keep cholesterol levels under control.

Fresh fruit. These "natural" desserts are high in fiber, vitamins, and minerals.

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VERSATILITY — THE CORE OF NEW COMPUTER PROGRAM FROM LILLY

A versatile new computer program designed to help pharmacists operate a more profitable pharmacy has been introduced by Eli Lilly and Company and Dista Products Company, Indianapolis, Indiana. Available to all retail pharmacists, it was recently previewed at the NARD convention in Louisville, Kentucky, where participants were treated to a "hands on" demonstration of the first unit, "Managing cash flow for increased profitability."

This new program will prove invaluable to the retail pharmacy. In addition to an explanation of the basic concepts of cash flow, the program covers topics, such as "sources and uses of cash" and "cash shrinkage." Also included are helpful hints for managing receivables, billing, and inventory — all arranged in a "user friendly" format. And the text on the screen is liberally illustrated with easy-to-understand flow charts and colorful bar graphs.

The versatile format of the program allows accessing pharmacists to evaluate their pharmacy's profitability status by performing multiple "what if" analyses. This "what if" structure enables pharmacists to enter their own pharmacy's financial data and then to manipulate the numbers in various ways in order to arrive at the most beneficial cash flow scheme.

In addition to its function as a learning and education tool, the new computer program can be used as a data storage bank. It can hold a substantial amount of data, with all information kept strictly confidential and inaccessible to anyone other than the designated operator. Thus, it is a truly cost-effective means for both learning and financial data storage.

Another special feature available through the new computer program is the free Lilly Analysis Service. Because a pharmacy's financial data reflect its strengths and weaknesses, it is extremely important that this information be properly interpreted and utilized. The purpose of the complimentary service is to locate areas that may present potential problems, offer suggestions for improvement, as well as to identify operations which are functioning well. By participating in the Lilly Analysis Service, the pharmacist can obtain the benefits of a "private" financial consulting firm without having to pay the high cost.

Any pharmacist wishing to participate merely inputs financial data on the program diskette provided and then sends the diskette to Lilly. After these figures are received, they are audited and a computer printout is generated. This printout is then analyzed by staff experts, comments are made, and the report is sent directly to the designated address. All data are kept *strictly confidential.* Again, there is no charge for this service.

With data submitted through the new computer program, Lilly publishes the *Lilly Digest.* The *Lilly Digest* is a compilation of operating statistics from independent retial pharmacies located throughout the United States. It is designed as an aid which pharmacy managers and owners may use in order to evaluate the operations of their own stores. Eli Lilly and Company publishes the *Lilly Digest* annually as a service to community pharmacy in the interest of sound business management.

The final element of this innovative disk program is the opportunity for continuing education credits. On completion of a test at the end of the unit, the pharmacist is awarded a certificate for 2 credit hours (ACPE), which are sent directly from Lilly.

Analysis, learning, and continuing education credits are only the primary components of this inaugural electronic interaction program for the pharmacist. Eli Lilly and Company and Dista Products Company are pleased to offer this dynamic new computer program, which is designed to help the independent retail pharmacist operate a more profitable and sound business.

Dickinson's Pharmacy

(Continued from page 29)

this. All I know is the present situation in pharmacy is ridiculous. Manufacturers and hired guns should not be trying to scare pharmacists with legal theories into giving them the market advantage they thought Congress could give them.

If you've got a beef, take it back to Mr. Waxman. That's what he's there for!

This feature is presented on a grant from G.D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G.D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G.D. Searle & Co.

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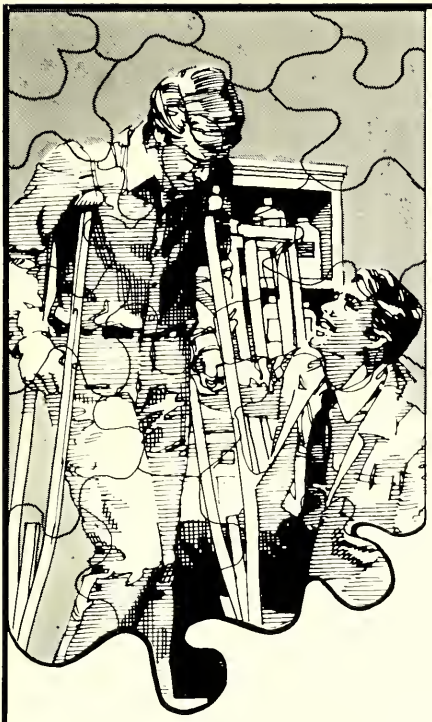

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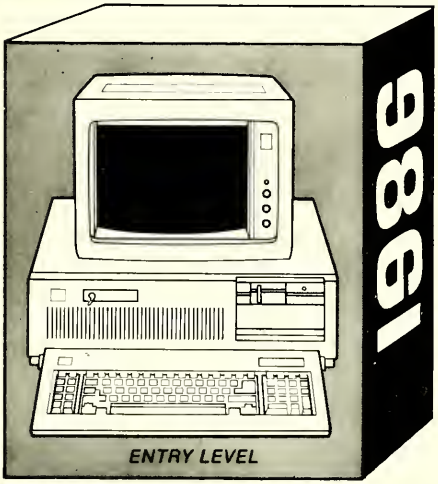

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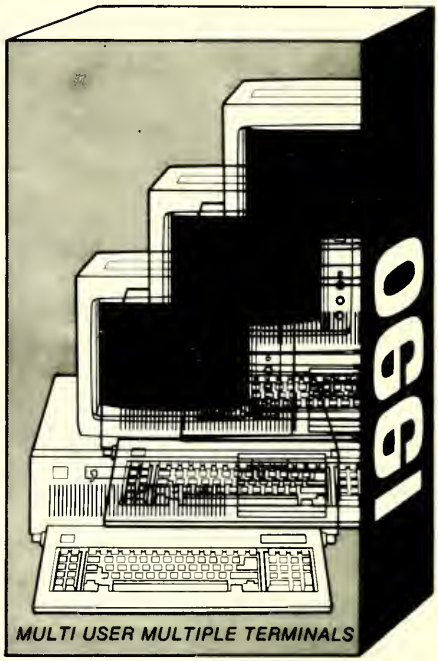

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Left to right: Immediate Past President H. Shelton Brown, Jr., presents the 1986 Mortar and Pestle Award to Jack G. Watts, with Mrs. Watts, at the Pharmacist-of-the-Year Dinner held in Burlington. Story on page 5.

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Current and former Eli Lilly representatives attending the Pharmacist-of-the-Year Dinner honoring Jack Watts

Recipients of the Mortar-and-Pestle Award. Left to right
Front row, Rheta Skolaut, Tom Burgiss, Hoy Moose, June West, Jack Watts, Jimmy Creech, Jean Provo and Harold Day. Back row, Milton Skolaut, Robert Hall, Bill Randall and John Henley

WATTS HONORED AS PHARMACIST-OF-THE-YEAR

Jack G. Watts, Burlington, was honored as the North Carolina Pharmaceutical Association 1986 Pharmacist of the Year at the Alamance County Country Club Friday night, September 5, 1986. He was presented the NCPhA Mortar-and-Pestle Award at the conclusion of the program attended by three hundred pharmacists, friends and relatives from across the state.

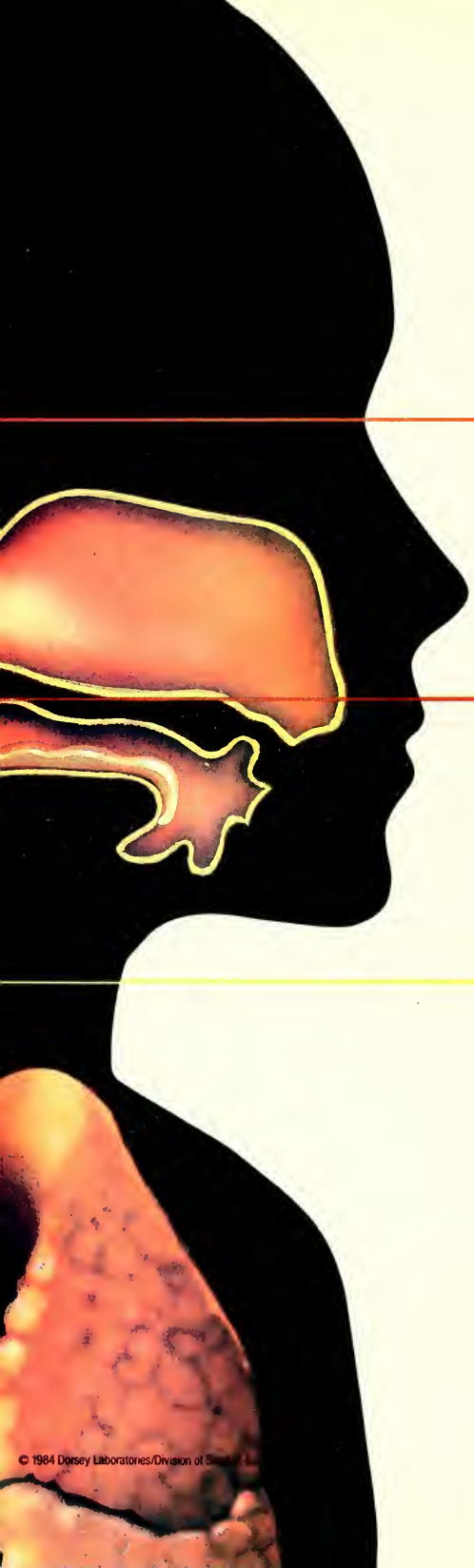
The Mortar-and-Pestle Award is presented annually by the NCPhA for distinguished service in pharmacy, pharmacy education, community activities and public health. Watts is a graduate of the University of South Carolina School of Pharmacy and worked as a sales representative for Eli Lilly and Company for 31 years before retiring in 1985. He is now serving as consulting pharmacist for the Alamance County Health Department and is the Coordinator of Continuing Pharmacy Education at the Greensboro Area Health Education Center.

NCPhA President M. Keith Fearing, Jr. was Master of Ceremonies for the program. Burlington Mayor K.L. Ketchum welcomed the out of town visitors to the city and presented a key to the city to President Fearing. Dr. Dale O. Steele, pastor of the First Baptist Church, delivered the invocation and tributes to Mr. Watts were given by Mitchell W. Watts, Dr. E.C. Sutton and A.H. Mebane, III.

Mickey Watts, cousin of the recipient and also a pharmacist, told of growing up under the tutelage of Jack Watts, learning each job in the drug store and learning how to make and keep money. He credited Jack with helping him stay on the path to pharmacy school. Dr. Sutton, a Burlington gynecologist and former general practitioner in Rockingham, said he was the first doctor Jack Watts called on when Watts first went to work for Eli Lilly. He told of Jack's batchelorhood in Rockingham and how it came to an end when he met Eloise Harrington. He also related several stories of house calls at night he and Jack went on. Mr. Mebane, Executive Director of the NCPhA, told of his experiences and impressions of Watts, both as a Lilly salesman who used to service Mebane's pharmacy, and as the 100th President of the North Carolina Pharmaceutical Association. He told of the many and varied areas of Watts' participation in professional activities in Burlington, the state and the nation.

David Hix, on behalf of the Alamance County Pharmaceutical Society, presented Mr. and Mrs. Watts with a grandfather clock as appreciation for his years of service to the society as secretary-treasurer. The Mortar-and-Pestle Award, symbol of the Pharmacist of the Year, was presented to Watts by H. Shelton Brown, Jr., the immediate past president of the North Carolina Pharmaceutical Association.

Program participants, left to right: Mickey Watts, Shelton Brown, Dr. E.C. Sutton, Jack Watts, Dr. Dale Steele, Mayor K.L. Ketchum, Keith Fearing and Al Mebane.



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COMMITTEE REPORT OF THE COMMITTEE ON PUBLIC HEALTH

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REPORT OF THE COMMITTEE ON PUBLIC HEALTH

The NCPhA Public Health Committee met at the Institute of Pharmacy on February 23, 1986 at two o'clock p.m., with Chairman Jerry D. Rhoades presiding. Of the fifteen members of the committee, the following were present: A.G. Hartzema, Stephen Caiola, E. Wilson Griffin, Edna Ruth Hadley, Seth Miller, James Oakley, and Charles Reed of the North Carolina Department of Public Health.

The topic of discussion was the pending enactment of an amendment to the Public Health Pharmacy Practice Act, which would allow registered nurses to dispense certain prescription drugs in Public Health Departments. Chairman Rhoades asked Charles Reed, a registered pharmacist employed by the North Carolina Department of Public Health, to explain to the members of the committee the legal aspects of the Bill and its implications for Pharmacy.

Mr. Reed provided each member with a copy of the ratified Bill, which will be voted on by the General Assembly at their next session. He explained that the Bill would require all Public Health Departments which dispense prescription drugs to obtain a Pharmacy permit and to dispense only those drugs listed in a Formulary approved by the Board of Pharmacy and by the North Carolina Department of Human Resources. The pharmacist of record would then be required to review the dispensing records at least weekly and to be responsible for the dispensing activity of the Public Health Department Clinics. Only the individual registered nurses authorized by the Board and the supervising pharmacist would be allowed to dispense prescription drugs.

After a brief question and answer period following Mr. Reed's explanation, the committee voted unanimously to recommend that the NCPhA Executive Committee support the Bill, with the following qualifications:

1.) The Formulary will be restricted to inclusion of
   (a.) Birth control/family planning drugs and devices
   (b.) Antituberculosis drugs
   (c.) Medications for treatment of sexually-transmitted diseases
   (d.) Prenatal vitamins/other nutritional supplements
   (e.) Vaccines/other immunization agents
2.) The pharmacist-manager, or another registered pharmacist under the direction of the pharmacist-manager, will provide at least six hours per week for records review and consultation with the Health Department.

There being no further business to come before the committee, the meeting was adjourned.

Respectfully submitted

Jerry D. Rhoades, Chairman
NCPhA Public Health Committee

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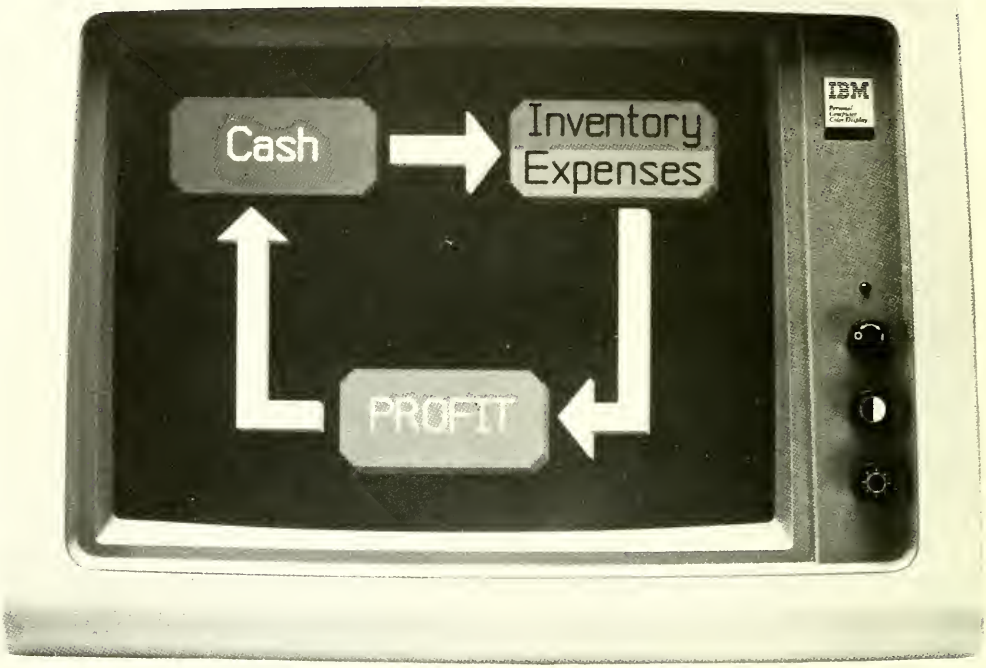

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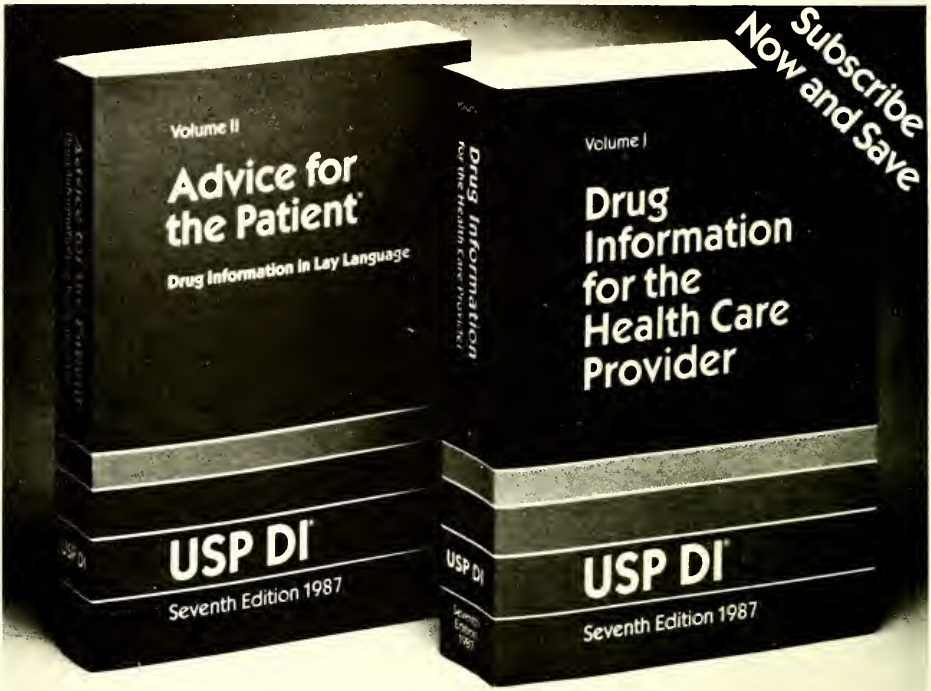

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THE EYES HAVE IT

There are so many behaviors implicated with today's three leading killers, cardiovascular disease, cancer and motor vehicle accidents, that reducing the risk of falling victim to these maladies may leave little time to think about safety and accident prevention.

What part of your body would you guess will receive the greatest percentage of injury? Your hands? Your head? Your feet? Your limbs? The *eyes* have it.

Think about this for a minute. Broken bones will mend. Lose a limb and a prosthesis can make you ambulatory again. Cuts, burns, bruises will heal. But you cannot see through a glass eye.

Statistics reveal that more than 1,000 eye accidents occur every working day each year and close to 100,000 may lose sight in one or both eyes. Forty percent of accidents that damage vision happen at home. How much thought do *you* give to protecting this most precious of gifts — *your sight?*

To start your thinking, examine the following list of hazards to your eyes. How many do you encounter on a regular bases?

- flying chips, fragments, splinters, particles from tools which break, fly off objects being worked on/hammered, or spin off during grinding activities
- splashes from molten leads, solder, acids, corrosives or sprays from insecticides, paint, herbicides and hair spray
- projectiles (some possibly traveling in excess of 200 mph):
  - (a) items thrown by lawnmowers
  - (b) objects used in sports, i.e., tennis, badminton, archery, racquetball, etc.
  - (c) games such as dart guns, air pistols, pea shooters
  - (d) materials resulting from explosions as in burning trash, celebrating with fireworks
- missiles formed by caps or corks from carbonated drinks, champagne or sparkling wines (gasses can exert pressure of 110 lbs. per square inch)
- pointed and sharp edges of toothpicks, pens, pencils, long fingernails, iris, yucca, holly plants, toys
- eye makeup carelessly applied (only protection is to exert extreme care)

This should give you the idea — danger to the eyes surrounds us. Gardening, arts and crafts, woodworking, sports and recreation can all increase risks to eyesight even though they are excellent antidotes to stress.

Regular glasses do not double as safety glasses (pieces of shatterproof glass and plastic have been removed from people's eyes). Your best investment is to purchase protective lenses which wrap around the sides of the temples to wear when indulging in risky activities. These can be purchased at hardware or sporting goods stores beginning for as little as $3.99 a pair.

One last word to contact wearers. The U.S. Centers for Disease Control in Atlanta reports a disturbing increase in the number of cases reported of a very rare and very serious eye infection. The new cases are almost exclusively associated with people who wear contact lens of all varieties, soft, hard, extended wear and daily wear. The infection, Acanthamoeba Keratitis, is very hard to diagnose and is often mistaken for other infections, such as herpes. Delayed treatment has resulted in the removal of the infected eyeball in two cases. The acanthamoeba is the most common free living amoeba in fresh water and soil. While no definite cause and effect has been found, evidence is beginning to point to contact lens users who try to make their own saline solutions. So once you have taken the plunge to splurge on contact lens, that is not the time to become frugal and to start cutting corners on care and treatment of the lens. It is imperative to follow closely the instructions for care given to you by the professional supplying the lens. And *always* start with clean hands.

From MEMO: Cost Management Vol. 2 No. 9

ENGLISH TEACHER POSITIONS IN JAPAN

Japanese pharmacy companies are rapidly becoming international. They are establishing offices in the U.S., Canada, and Europe.

International Education Services (I.E.S.) works with many of Japan's top pharmaceutical houses in providing training on various aspects of drug testing, marketing and licensing.

Headquartered in mid-town Tokyo with a branch office in Osaka, I.E.S. has begun the 1987 recruitment drive for individuals with pharmacological training and/or experience to teach English. Selected applicants will be given a wide range of classes to teach in various fields of business. Persons with backgrounds such as pharmacy may be assigned specifically to teach special pharmaceutical English courses.

Those interested in a rewarding experience working and living in Japan should write for further information to IES, Shin-Taiso Building, 10-7, Dogenzaka 2-chome, Shibuya-ku, Tokyo 150, Japan.

CORRESPONDENCE COURSE

ADVISING CONSUMERS ON OTC EYE PRODUCTS. PART I: THE EYE AND ITS DISORDERS

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati, Cincinnati, OH
and
Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University, Ada, OH

Goals

The goals of this lesson are to:
1. discuss the physiology and function of the eye
2. explain how to treat self-treatable eye disorders.

Objectives

At the completion of this lesson, the successful participant will be able to:
1. identify the different parts of the eye and their functions;
2. choose the appropriate OTC agents to self-treat eye disorders;
3. refer the patient to a physician when appropriate.

Consumers frequently seek the advice of pharmacists to relieve discomfort and treat diseases of the eye. The eye is a delicate instrument and even minor symptoms may signal the beginning of more serious problems. The pharmacist must, therefore, take care in his professional decision to refer the patient to an ophthalmologist or suggest self-treatment.

The first segment of this series of lessons on OTC eye preparations will review the function of the eye and the few conditions considered to be self-treatable.

Physiology And Function Of The Human Eye

The eye is comprised of a large number of specialized cells and tissues (Figure 1), each of which serves a specific function. Beginning from the outside and working inward, the **cornea** is the clear, transparent, lipid portion of the outer coating of the eyeball which forms the anterior wall of the aqueous chamber. It is comprised of five layers of tissue, the outermost (epithelium) and innermost (endothelium) of which are lipophilic. This means that the cells of these two tissues repel water. The mid sections of the cornea are hydrophilic and contain water. The lipophilic nature of the cornea is an important feature in relation to the absorption of eye drops and the wearing of contact lenses. This will be discussed in more detail later.

The cornea is the initial tissue through which light rays must pass the reach the retina. There must not be any opacities or interference such as deflection or reflection. Therefore, corneal cells are clear and transparent. The cornea is kept shiny and lubricated by the tear fluids which moisten its surface and fill in any irregularities in the epithelium which can rapidly regenerate itself. Unless it is diseased, the corneal epithelium has the capacity of covering abrasions within 24 hours. Unlike most other tissues, a healthy cornea will heal without leaving a scar.

There are no blood vessels in the cornea, but there is a high number of nerve fibers which make it one of the body's most sensitive organs. Since the cornea is transparent, one sees the iris and its

Rx in the service of pharmacy

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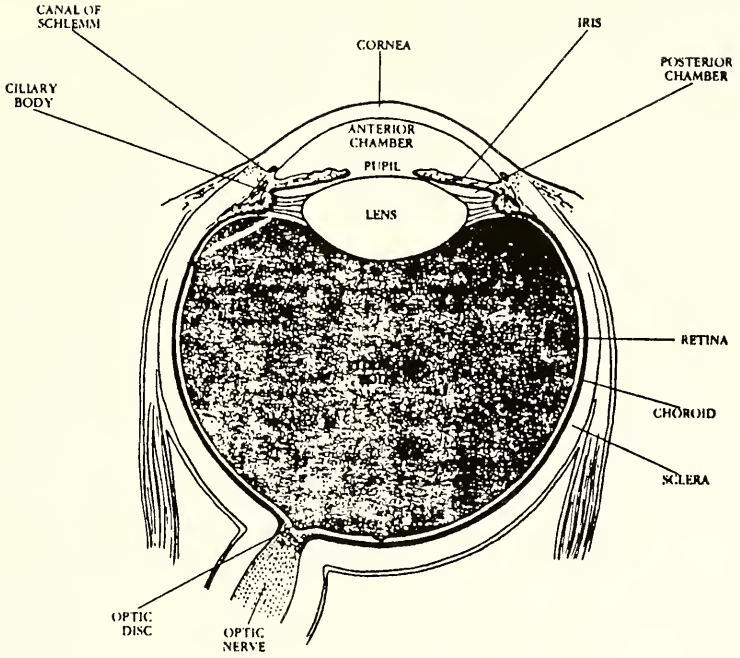

FIGURE 1.

center black opening, the pupil. The cornea is circular and fits like a watchglass into the double edge of the sclera.

The **sclera** is the white part of the eye that forms a relatively tough covering. Along with the cornea, it constitutes the external protective covering of the eye. The sclera, which makes up the greatest portion of the external eye, is covered by a filmy, moist membrane called the **conjunctiva.** It extends from the junction of the cornea and the sclera outward to the margins of the eyelid.

The conjunctiva is a thin transparent layer of mucous membrane which lines the posterior portion of the eyelids and the anterior portion of the sclera. It is responsible for supplying blood, nutrition and oxygen to the corneal tissues, and for removing waste products. The conjunctiva plays a major role in maintaining the health of the cornea.

The **anterior chamber** is the space bounded in the front by the cornea and behind by the iris. It is filled with **aqueous humor,** a clear, watery fluid

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which fills the anterior chamber within the frontal part of the eye.

The **iris** is a colored, circular membrane suspended behind the cornea, immediately in front of the lens. The iris is connected to the ciliary body and separates the anterior and posterior chambers of the eye. The black hole in the center of the iris is the **pupil** which reflexly controls the amount of light admitted to the retina. The iris and pupil act as a shutter. In the bright light, the pupil constricts. In dim light, the pupil dilates.

The color of the iris depends on the amount of melanin it contains. If only a small amount is present, the reflection from the pigment on the posterior layer is scattered and the iris appears blue. With a moderate amount, the iris will be hazel, and with a large amount of melanin the iris will appear brown.

The **crystalline lens** is a transparent, colorless, biconvex structure which is suspended from the ciliary body. It lies between the aqueous and vitreous humors and functions to focus the rays of light coming through it onto the retina. The crystalline lens has no direct blood supply. It is nourished by the aqueous humor.

The **ciliary body** is a thin muscle which is responsible for accommodation. It performs this function by controlling constriction and dilation of the iris and the refractory power of the crystalliine lens. The ciliary body also secretes aqueous humor.

The **posterior chamber** of the eye forms the space between the back of the iris and the front of the crystalline lens. Like the anterior chamber, it is filled with aqueous humor.

Two other important types of tissue in the anterior eye are the trabecular meshwork and Canal of Schlemm. The **trabecular meshwork** is a porous-like structure surrounding the entire circumference of the anterior chamber. Aqueous humor flows through it into the Canal of Schlemm.

The **Canal of Schlemm** is an oval-shaped channel that also surrounds the anterior chamber

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outside the trabecular meshwork. It is situated at the juncture of the sclera and the cornea. It is through this canal that aqueous humor is excreted after it has circulated between the lens and the iris, and between the iris and the cornea. The Canal of Schlemm is connected with the venous blood supply.

The area immediately behind the crystalline lens is filled with **vitreous humor.** This is a transparent, colorless mass of soft gelatinous material that fills in the eyeball and holds the lens and retina in place. Functionally, the vitreous humor is inactive. It can be likened to the space between the lens and the film in a camera. Sometimes small particles form within the vitreous humor and show up in the field of sight as opacities, more commonly called "spots."

In the posterior portions of the eye, two of the major tissues are the choroid and retina. The **choroid** is the vascular bed which provides the blood supply to the retina. The **retina** is the innermost coating of the eye. It contains the light-sensitive nerve elements. It is comprised of two distinct types of cells called rods and cones.

Visual acuity and color discrimination are functions of the cones, while the rods are responsible for determining motion and vision at low degrees of illumination. If the cones do not function, the individual is color blind. If the rods do not function, the resulting condition is night blindness.

Depth perception and accommodation result from each eye seeing an object at a slightly different angle. Through the **optic nerve,** the brain fuses slightly dissimilar images. The combination of these angular views provides depth perception. Accommodation is the adjustment of the eye for seeing objects at different distances, and is accomplished by changing the shape of the crystalline lens through the action of the ciliary muscle contracts. This in turn changes the shape of the lens, therefore increasing its refractory power. When objects move away, the opposite action occurs.

Color vision is made possible because the cone cells in the retina contain three photosensitive pigments in their outer portions. As they absorb light rays of various wavelengths, i.e., red, yellow and blue (the primary colors), the pigments mix together to form all of the colors of the spectrum and pass these impulses on to the optic nerve through chemical reactions.

Errors in Accommodation

Although the following conditions will be discussed in much more detail in a future lesson on contact lenses, they will be defined here.

Astigmatism is a condition in which the cornea is not perfectly spherical. Because of this, there is a refractive error which prevents light rays from converging to a single focus on the retina.

Hyperopia, more commonly called far-sightedness, is a refractive error in which the focus for the rays of light coming from a distant object occurs at a point behind the retina. This causes blurred vision.

The opposite of this condition is **myopia,** or near-sightedness. In this instance, a refractive error causes the point of focus for rays of light coming from distant objects to be in front of the retina. Vision is blurred for distant objects.

All three of these conditions can be easily corrected by placing an artificial lens, i.e., spectacles or contacts, between the object and the cornea.

Presbyopia is a gradual lessening of the power of accommodation due to the physiological changes of aging. It becomes more noticeable after age 40 by virtue of blurred near-vision. As people age, the contractile ability of the ciliary muscles decreases and accommodation of close-up objects suffers.

Photophobia is an abnormal sensitivity to and discomfort from light. At times, it can become so severe that the affected individual is afraid to enter brightly lit areas.

A **cataract** occurs when the crystalline lens of the eye, which is normally transparent, becomes opaque due to the precipitation of foreign substances, or direct damage as a result of a disease or trauma. The removal of the cataract is referred to as **aphakia** which basically refers to the absence of the lens of the eye.

Self-Treatable Eye Disorders

There are very few disorders of the eye that can be correctly self-diagnosed and/or self-treated (Table 1). Except for tear insufficiency and minor irritation, the eye preparations available without a prescription merely provide symptomatic relief.

Problems arise when persons misdiagnose their conditions. Usually they find a product via trial and error, that relieves their condition. The condition may worsen, or it may prevent early definitive physician-initiated therapy with the correct drug. For this reason, it is best to stop

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using the OTC product and contact a physician if the condition does not respond within a few days.

There are three ocular conditions that are generally considered to be self-treatable: tear deficiency, corneal edema and minor inflammation and irritation.

Tear deficiency results from inadequate production of lacrimal and ocular secretions. Since the epithelial layer of the cornea is hydrophobic, it repels water. However, the corneal tissues require water and its absence for just a few moments can lead to the onset of corneal deterioration.

Tear film is made up of three layers of substances, the components of which are listed in Table 2. The innermost layer of **mucin** is deposited by the conjunctiva as the eyelid blinks. Mucin adheres to the corneal surface, lowers its surface tension, and converts it from a totally hydrophobic to a relatively hydrophilic mode so that the lacrimal secretion, which is basically normal saline, can spread over the cornea.

The lacrimal secretion, i.e., the **aqueous layer** of tear film, contains the key components for corneal nutrition and metabolism as well as antimicrobial lysosomes. These are substances that lyse or destroy microbial cells.

The outermost layer of tear film, **lipid layer,** is also supplied by the conjunctiva. It provides stability to the lacrimal secretion, prevents rapid evaporation, holds it there for awhile, and spreads it over the cornea.

Dry eye syndrome resulting from tear deficiency can be extremely painful when non-wetted areas of the cornea are continually exposed to atmospheric irritation and mechanical irritation from blinking. Artificial tear products are intended to adsorb onto the cornea, increase viscosity, and provide pain relief. Periodic moist compresses are also helpful as is raising the humidity of environmental air. Severe cases may require a corneal bandage type of contact lens.

The ocular demulcents and emolients are useful in alleviating the burning discomfort and dry feeling associated with tear deficiency. While there are causes of tear deficiency that need supervision, its treatment usually involves long-term use of ocular lubricants. Except for special drug delivery systems such as the Lacrisert™, there are no prescription-only tear deficiency products that are clearly more effective than the OTC demulcents and emollients.

TABLE 1
Self-Treatable and Non-Self-Treatable Ocular Conditions*

Self-Treatable	Corneal edema**
	Minor inflammation
	Minor irritation
	Tear deficiency
Non-Self-Treatable	Corneal ulcers
	Embedded foreign bodies
	Flash burns
	Glaucoma
	Infections
	Uveitis

*As determined by the FDA Advisory Panel on OTC Ophthalmological Drugs
**After diagnosis by a physician

TABLE 2
Components of Tear Film

Mucin Layer	Glycoproteins — chemicals composed of carbohydrates and proteins
Aqueous Layer	Albumin
	Amino acids
	Bicarbonate
	Chloride
	Glucose
	Lysosomes
	Phosphate
	Potassium
	Sodium
	Urea
	Water
Lipid Layer	Fatty alcohols
	Lecithin
	Non-polar lipids
	Phospholipids
	Triglycerides

Corneal edema cannot be self-diagnosed. It is a condition that involves excessive water inside the epithelial and endothelial layers of the cornea. This leads to swelling of the corneal tissues and impaired vision. Symptoms include foggy vision and/or haloes around light, irritation, photophobia and excruciating pain. The condition can result from a number of underlying causes such as glaucoma, degeneration of corneal cells, inflammation of the iris, other ocular inflammations, infection, and excessive wearing of contact lenses. In each instance, the cause must be corrected. Hypertonic agents, e.g., 5% sodium chloride, are recommended for temporary relief of corneal edema, and can be purchased without a prescrip-

tion. However, a physician must first diagnose the condition and institute corrective therapy.

Minor irritation and inflammation of the eye are most often exhibited by burning, itching, smarting, tearing and redness. These symptoms can be alleviated with a simple eyewash, astringent, demulcent, emollient or vasoconstrictor. The types of ocular inflammation and irritation which are amenable to self-medication with OTC eye preparations are those caused by the presence of loose, easily removed foreign particles, air borne pollutants such as cigarette smoke and allergens, and chlorinated water in swimming pools.

Foreign bodies should be removed by a professional to prevent damage to delicate eye parts. The following conditions are also not appropriate for self-medication: uveitis, which is inflammation of the cornea; and corenal ulcers, which can cause blindness if not treated properly. Glaucoma and flash burns are also not self-treatable.

Flash burns are also called "welder's eye" and result from ultraviolet radiation burns from welding equipment when the eyes are not properly protected. Minor flash burns are self-limiting but not self-treatable. They often heal if the eye is rested under an eye patch. When treatment is initiated, it generally involves topical antibiotics, cycloplegics, and systemic analgesics.

Styes, Pink Eye And Crusty Eyelids

These conditions are in the "twilight zone" of therapy since there are no proven, effective anti-infective agents safe for OTC use. The best advice is to suggest that the individual see a doctor. However, we know that this advice will often not be followed, so the next section is offered to assist the pharmacist in making good professional judgement.

A **stye** (hordeoleum) results from an infection with pathogenic staphylococci in sebaceous or sweat glands, or from an eyelash follicle in the margin of the eyelid (bleph). This is exhibited by localized tenderness, redness, swelling, and possibly, pus formation. When pus is present, the infective organisms are invariably staphylococci. The condition can be treated with warm water or saline compresses to "draw" the accumulated pustular material and bacterial colony to the surface. When this comes to a head, the pustule (pimple) can be carefully lanced and expressed. Premature squeezing or pressing of the postule can lead to spread of infection into the subdermal or adjoining areas. The effective anti-infective agents, such as bacitracin or the sulfonamides, are considered to be unsafe for over-the-counter use. Minor conditions are self-limiting and much of the irritation can be alleviated by applying an OTC demulcent or emollient such as petrolatum/yellow wax to be discussed in the next lesson of this series on OTC eye preparations.

The crusty material that accumulates on the eyelids due to inflammation (blepharitis) results from exudation from overactive sebaceous glands, bacterial by-products, or both. These causes can be differentiated since the seborrheic crusts are usually oily while the staph-induced type produces dry scales and small ulcerations in the surrounding tissues.

Treatment of staphylococci-induced blepharitis involves moist compresses to soften and remove the scales, and the application of an appropriate antibiotic, none of which are available OTC. The seborrheic form of blepharitis requires correction of the underlying scalp problem that is adding to the excess sebum in the area. This is generally accomplished by good hygiene and the use of OTC anti-seborrheic shampoos.

Pink eye is actually conjunctivitis due to infection by bacteria, fungi or viruses, or to an

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CORRESPONDENCE COURSE

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allergic reaction. It is commonly called pink eye because of the redness of the sclera along with exudation and a feeling of sand in the eye. Proper treatment requires identification of the causative organisms and use of an appropriate antiinfective agent. The milder forms are self-limiting and will clear in a few days with or without treatment. The more serious cases require proper treatment to avoid secondary corneal infections, corneal destruction or blindness. In milder cases, OTC eye demulcents, emollients, astringents and vasoconstrictors are generally helpful. These will be discussed in more detail in the next lesson in this series. The importance of contacting a physician if any eye condition does not clear within a few days of self-treatment will be stressed again.

A common cause of eye irritation resulting in the aforementioned conditions is cosmetic agents. Mascara and other eye make-up product applicators often become contaminated with microorganisms. Women with signs and symptoms of blepharitis or conjunctivitis, especially if recurrent, should be warned that the cause may be their eye cosmetics. Mascara should certainly not be used to hide blepharitis because it may further aggravate and prolong the condition. It may be helpful to replace mascara applicators frequently. Continual use of ocular vasoconstrictors is merely a cover-up of the underlying cause.

Ecchymosis is a "black eye." It is best treated by applying an icepack.

Please turn to
Correspondence Course Quiz on Page 28.

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DICKINSON'S PHARMACY

by Jim Dickinson

Government thieves. This is important. Go to your typewriter, word-processor or pencil as soon as you're done reading this. You'll see why.

First, though, ask yourself: Does Medicaid deserve a discount from pharmacy? If your answer is a firm, resounding "Yes!" please read no further.

"Discount" is the buzzword of the year. You remember how federal Medicaid discovered that pharmacies get prompt payment discounts off list price, and how Average Wholesale Price isn't the same as list, because of discount-type things.

Those pharmacies are getting away with murder, the feds said, in shock — we want those discounts! So they dreamed up schemes to confiscate them, telling their regional offices to go get 'em, by whatever means it took.

You remember how, last year, the south-west Medicaid region announced mandatory discounts, state by state, and how, while all the pharmacy groups went to the wall with a lawsuit in Washington, Texas got stuck with a discount off AWP that it's still living with.

The legal confrontation in Washington was an outstanding victory for pharmacy and its friends in industry who joined in — a rare, thrilling example of "united we stand, divided we fall."

But, when you're fighting the federal Medicaid bureaucrats, no win lasts for long.

These officials for over a decade have successfully defied law and order by refusing to yield to either political or judicial direction. They have a one-track mind. They duck their heads, turn their other cheek, stand their ground, step aside, dodge and weave — but they're always, always there. Blilnd, deaf and dumb, they stand there, right where they've always been like some giant tree stump, endlessly convinced of one thing and one thing only: pharmacies have got money that should be theirs.

Resuming — as you surely knew they would — their single-purpose campaign to dredge more money out of pharmacy, the federal Medicaid bureaucrats have devised three alternatives to their unfair and, finally, unworkable MAC-EAC program. These crafty new devils are called PhiP (Pharmacy Incentive Program), CIP (Competition Incentive Program) and Modified MAC. They *don't* offer more money to pharmacy!

They were rushed into the Washington bullpit for fast discussion and implementation before all the cost-savings analyses were completed.

As these draft analyses slither out of their thinktanks now, we can begin to see a bottom line taking shape in them — it equals about a 10% discount off average "private pay" Rx retail prices.

Nothing is firm, sharp and distinct, mind you. These are "preliminary" figures, and "draft" analyses, you understand. It would be wrong to criticize them. They're just for discussion, while the final program is decided upon elsewhere!

The National Association of Chain Drug Stores in October rendered a signal service to pharmacy by commissioning University of Chicago Law Professor Paul M. Bator to report on all the laws that federal Medicaid has been twisting, if not breaking, in its dishonest profit-confiscation efforts.

Citing 42 CFR Sec. 447.204 in the Medicaid regulations where it says "The [state Medicaid] agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients *at least to the extent that those services are available to the general population"* (emphasis added), Bator laid it out:

"Accordingly," he reported, "the regulations explicitly require that, to the extent that medical services to the 'general population' are conventionally provided by for-profit enterprises, these enterprises must be reimbursed at a level 'sufficient to enlist' their participation in the Medicaid program — something that is manifestly impossible unless efficient providers are allowed to make a fair profit."

Bator noted that some pharmacies have refused to do business with Medicaid, and those that continue to do so are motivated by factors such as public-spiritedness or a desire not to incur adverse publicity by a refusal to serve the poor —"it must be acknowledged that there is substantial societal pressure on drug stores to participate in the Medicaid program."

It's entirely inconsistent with Medicaid's philosophy, Bator wrote, that non-Medicaid patients should subsidi_ aid patients in the cost of their prescriptions, or that pharmacy's reasonable profits should be confiscated.

You know that Bator has put it on the line, right where it belongs. Government confiscation of private property is what it boils down to. It may be cloaked in legal garb, but it really is theft.

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DICKINSON'S PHARMACY

Continued from page 21

Your money is being stolen by government thieves, even before you get it.

Now you know what to do with your typewriter, word-processor and pencil. Mail your views to Donald Newman — a former independent pharmacist, who surely understands. He's also the current Undersecretary at HHS (Room 614G, Humbert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201).

I'm not sure about this, but he might have the power to make the federal Medicaid bureaucrats stop it. Nobody else has ever been able to tell them and make it stick, but it's worth a shot.

This feature is presented on a grant from Mylan Pharmaceuticals, in the interests of promoting the open discussion of professional issues in pharmacy. Mylan Pharmaceuticals accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of Mylan Pharmaceuticals.

Jim Dickinson is president of Ferdic, Inc., a West Virginia corporation and is a widely read correspondent for pharmaceutical and health related publications worldwide. He is a native of Australia where he edited and published the *Australian Journal of Pharmacy* for six years. He was formerly Washington bureau chief for *Drug Topics Magazine* and has served as special consultant to NARD and special assistant to the executive director of APhA. He was managing editor of the *Green Sheet* and senior editor of *The Pink Sheet,* both pharmacy news and pharmacy industry newsletters.

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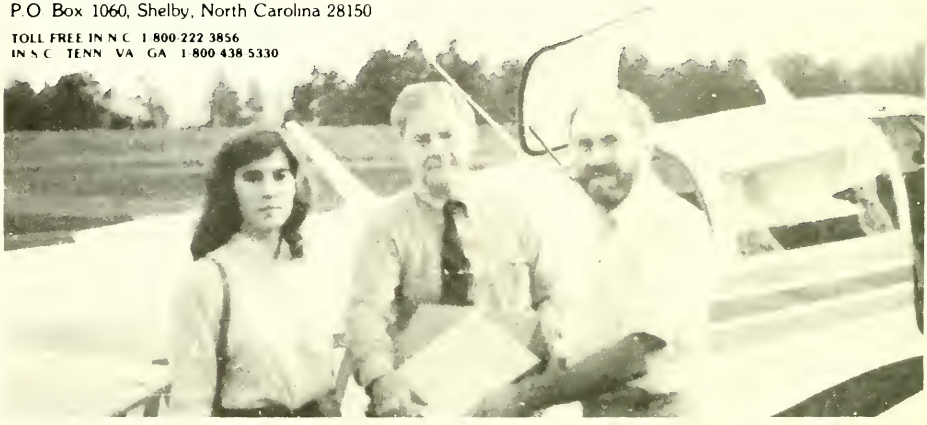

RESETTING YOUR BIOLOGICAL CLOCK: THE SCIENCE OF CHRONOBIOLOGY

by Charles P. Pollak, M.D.
Acting Director, Institute of Chronobiology
New York Hospital-Cornell Medical Center
White Plains, NY

"The time is out of joint: — O cursed spite
That ever I was born to set it right!"
Shakespeare

These and countless other lines signify how, intuitively, we recognize that our lives are influenced by time and season.

Now scientists are finding evidence to support the poets. For example, are you:

- A "morning person," brimming with energy and accomplishing mountains of work while others are still ungluing sleepy eyes?
- A "night person" who comes alive when the rest of the world takes to bed?
- An insomniac who awakens in the wee hours and tosses and turns thinking about your troubles?
- A "seasonal depressive" who is downcast in winter?
- A frequent traveler, discombobulated by jet lag?
- A shift worker who is thrown out of sync every time your job schedule is rotated?
- A wintertime "fatty" — like an animal prepared to hibernate — and do you shed weight during the summer?
- Sexier in the spring?
- Sluggish after lunch, so you wish you lived in a culture that has a siesta time?

Chronobiology: "Its Hour Come Round at Last"

These situations and many others are believed to reflect both the normal operations and some familiar disruptions of our biological clocks. Chronobiology is the field of science and medicine that explores the many bodily changes governed by the hours and the seasons.

Our bodies have internal rhythms that make us sleepy at night, allow us to awake alert in the morning, cause us to grow hungry at mealtimes, and produce low body temperature in the middle of the night that rises to a high point in the daytime. A variety of hormones ebb and flow like clockwork. Nearly every function of the body exhibits a 25-hour pattern. As one team of researchers put it: "Our biological rhythms make each of us a microcosm of the geophysical world."

The link to the outside world in creating these bodily rhythms may be quite specific. Investigators are finding, for example, that exposure to light can reset the biological clocks that regulate many body functions. Light or dark falling on the eyes transmits messages to the pineal gland of the brain, orchestrating a great variety of hormonal activities. These hormones affect sleep, hunger, sexual desire, moods, temperature, alertness, thinking . . . indeed, almost everything.

Many experiments with animals indicate that changing the duration of light in their environments or eliminating the pineal light/dark regulator puts them out of synchrony with nature. They don't mate at the usual time, birds may not migrate, deers' antlers grow in the wrong season and animals don't hibernate.

Some key human disturbances are being studied and treated in the Institute of Chronobiology at New York Hospital-Cornell Medical Center in White Plains, NY, and quite a few other research facilities around the world.

Delayed Sleep Phase Syndrome — a Form of Insomnia

Left to itself, our bodies tend to run on a slightly longer schedule than 24 hours — a 25-hour cycle. Some mechanism continually resets our biological clocks so that most of us can go to sleep at the same time as the night before even though our bodies could hang in for another hour, and we agree to wake up even though forces within us lobby to sleep later.

Conflict between natural biological rhythms and adjustments required by life's demands may be responsible for a type of insomnia called

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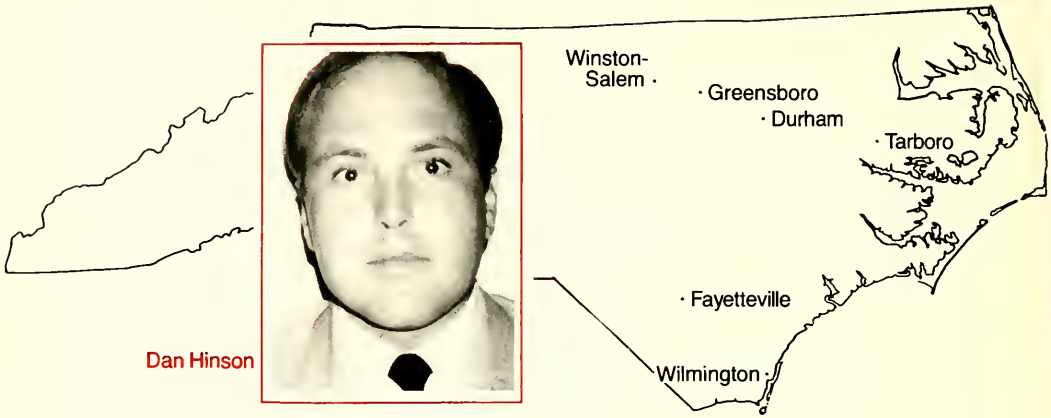

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BIOLOGICAL CLOCK

Continued from page 23

delayed sleep phase insomnia. People with this condition are consistently unable to fall asleep at the desired time. They tend to be extreme "night owls," and often feel most productive late at night. They often have neither the ability nor the desire to sleep until 3 or 4 a.m. And once asleep, they virtually need explosives to get them up for work in the 9-to-5 world. If they fall asleep at 3 a.m. and are forced to rise at 7 a.m., the problem remains; exhaustion won't reset the biologic clock.

A treatment approach that has helped is going to sleep progressively *later.* On the first night, instead of 3 a.m., the person holds off until 6 a.m. He or she gets the normal amount of sleep, waking up at perhaps 1 p.m. The next night, sleeping and waking are put off yet another three hours. This is continued until the desired bedtime is reached.

Once the inner clock is on the same schedule as "outer time" and living requirements, the person must stick to it, since regularity is critical to maintaining the time frame.

Depression and Insomnia

Many people with depression fall asleep promptly, but wake up long before dawn. These people also have a disturbed pattern of sleep that scientists can monitor.

Frederick K. Goodwin, M.D., and Thomas A. Wehr, M.D., of the National Institute of Mental Health in Bethesda, Md., propose that the timing of these patients' sleep stages is advanced: Sleep stages that normally occur near the end of sleep happen instead at the beginning. Studies in which the researchers systematically wake these people early, depriving them of some sleep, have helped restore normal sleep patterns and relieve depression.

There are other clues linking depression to malfunctions of our biological clocks. For one, it generally occurs in cycles — running its course, disappearing, then returning at a future time. Depression is often worse in the morning and lifts as the day progresses.

There are also seasonal variations —April being, indeed, the cruelest month. Springtime is the season of the most hospital admissions for depression, the most electroconvulsive (shock) treatments for severe depression and the most suicides. These all suggesst that some annual biological rhythms or other factors influence some psychiatric disorders.

Seasonal Depression

For one form of depression April is the *kindest* month. Psychiatrists have identified a type of winter doldrums — genuine depression, but not of suicidal proportions — that occur in winter and disappear in spring. Termed seasonal affective disorders (SAD), it may be a result of diminished light in winter. Many SAD victims get better when they go south during the winter to latitudes that are more spring-like.

One treatment has been to fool the body into thinking it's a different season. Norman E. Rosenthal, M.D., of the National Institute of Mental Health, has been exposing winter depressives to very bright, movie-set type lights for several hours, morning and night, to lengthen the days of fall and winter. Many depressions have abated.

Other Types of Insomnia

Some types of insomnia are related to our biological clocks, others are not. Older people tend to take naps during the day and can't sleep through the night. Scientists find that older body clocks seem to speed up. Perhaps they run so fast that they can't synchronize with a 24-hour day. Shift workers, such as policemen and firefighters, who get switched from days to nights, as well as those who moonlight on second jobs, also tend to have sleep difficulties. Both groups have biological rhythms out of tune with their schedules.

There are also many other causes of insomnia, unrelated to biological rhythms. Doctors can manage many of these or can refer patients to sleep disorder specialists.

Jet Lag Calls for Readjustment

Those traveling to different time zones must adjust to the new times for night and day, then must readjust once they are home. The strategy to prevent problems depends on the trip. Someone going to a different time zone for a *brief* stay should *avoid* adjusting to the local time.

If one is to be in the new setting for a couple of

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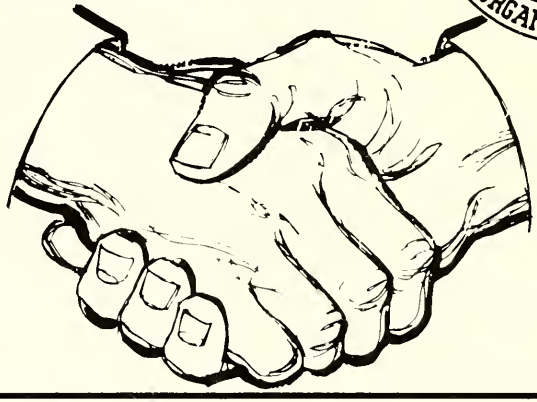

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BIOLOGICAL CLOCK

Continued from page 25

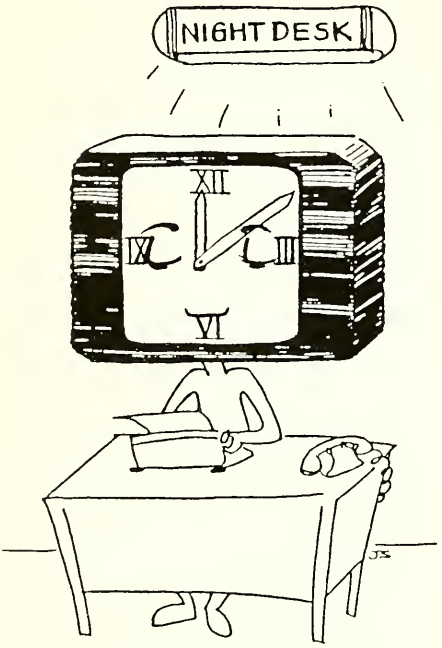
weeks, it's best to adjust quickly. Get involved in its schedules. Be exposed to its light and dark. Delay going to sleep in order to get in step.

Travel in a westward direction is easier for most people's biological clock adjustments than travel to the east. Traveling west means longer days, which is what our bodies want anyway. Then, by denying oneself some sleep, it's easy to fit into local patterns.

Traveling eastward means shortening the day. This can be both difficult and stressful.

Among the remedies being tested are short-acting sleep medications taken for a few nights. Recent studies have shown these to be promising as aids to time-zone or work-schedule adjustments. But further studies are necessary before we can be certain how best to handle these changes. Handle them we must, however, as travel for business and rotating work shifts becomes ever more common.

Chronobiology is aimed at unraveling these and the many other mysteries of emotions and functions that are linked to our inner biological clocks.



DRUG CO-PAYMENT FOR STATE PLAN MEMBERS

On July 15, 1986, the North Carolina General Assembly enacted changes in the Comprehensive Major Medical Plan for Teachers and State Employees. One important change involves the reimbursement of prescription drugs.

Prescription drugs purchased on or after January 1, 1987, are subject to a $3.00 co-payment per prescription for brand name drugs and a $2.00 co-payment per prescription for generic drugs or drugs with no generic equivalent. This co-payment does not apply to the annual coinsurance maximum. After this co-payment is taken, any reimbursement would also be subject to annual deductible and coinsurance amounts.

To accurately apply the co-payment, please indicate on the pharmacy claim or receipt the following:

"B" — brand name drugs
"G" — generic drugs or drugs without generic equivalent

This indicator should be printed beside each drug number on the claim or receipt.

Reimbursement to you will not change, if you do not file claims for State Plan members. Plan members will pay you and then file for their reimbursement.

The $2.00 or $3.00 co-payment will be applied when the claim or receipt is processed. If you are filing claims, you will notice that these amounts have been deducted on your voucher (Processed Claims Register). If the Plan member files your receipts, he/she will notice that these amounts have been deducted on his/her voucher (Explanation of Benefit form).

If you have any questions regarding this change in prescription drug reimbursement or have other concerns about the State Health Plan, you may contact the Claims Processing Contractor at the following address and telephone numbers. These numbers are for *provider use only* as members have their own separate numbers.

EDS Corporation
Claims Processing Contractor
Post Office Box 30050
Raleigh, NC 27622

Monday through Friday (8:15 a.m.–4:30 p.m.)

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CORRESPONDENCE COURSE QUIZ

The Eye and Its Disorders

1. The tissue that surrounds the entire circumference of the anterior chamber of the eye and allows aqueous humor to flow into the Canal of Schlemm is the:
   a. choroid.
   b. ciliary body.
   c. trabecular meshwork.
   d. sclera.

2. Near-sightedness is synonymous with the term:
   a. astigmatism.
   b. hyperopia.
   c. myopia.
   d. presbyopia.

3. The infective organism that is most likely to be the causative agent of blepharitis is:
   a. proteus.
   b. pseudomonas.
   c. staphylococcus.
   d. streptococcus.

4. Which of the following is a true statement?
   a. The entire five layers of the cornea are lipophilic in that they will not take on water.
   b. The cornea is covered by epithelial tissue called the conjunctiva.
   c. The corneal cells receive their nutrition and oxygen directly from blood vessels running through the cornea.
   d. The cornea is circular and fits like a watchglass into the double edges of the sclera.

5. All of the following are considered to be self-treatable with OTC products EXCEPT:
   a. corneal edema.
   b. minor irritation.
   c. tear deficiency.
   d. welder's eye.

6. The lay person's term "stye" refers to a condition called:
   a. ecchymosis.
   b. hordeoleum.
   c. flash burn.
   d. uveitis.

7. The type of blepharitis that results in dry scales and crusts, and small ulcerations in the surrounding tissue is most likely caused by:
   a. bacterial infection.
   b. corneal edema.
   c. inadequate tear secretion.
   d. overactive sebaceous glands.

8. The thin muscle that constricts and dilates the iris and crystalline lens to allow for accommodation of vision is called the:
   a. choroid.
   b. ciliary body.
   c. trabecular meshwork.
   d. sclera.

9. Which of the following would most likely provide relief from corneal edema?
   a. 0.9% sodium chloride
   b. 5% sodium chloride
   c. 25% petrolatum
   d. 50% petrolatum.

10. All of the following statements are true EXCEPT:
    a. the cone cells of the retina allow for visual acuity and color discrimination.
    b. accommodation results from each eye seeing distant and close-up objects at the exact same angle of vision.
    c. the rod cells of the retina allow for the determination of motion and vision at low degrees of illumination.
    d. color vision is made possible by the retinal cells mixing three photosensitive pigments together.

11. Glycoproteins are the predominant component of which of the following layers of tear film?
    a. Aqueous
    b. Lipid
    c. Mucin

12. The white part of the eye that forms a relatively tough covering is called the:
    a. choroid.
    b. ciliary body.
    c. trabecular meshwork.
    d. sclera.

13. Which of the following OTC products is LEAST likely to alleviate minor inflammation of the eye?
    a. Antimicrobials.
    b. Astringents.
    c. Emollients.
    d. Vasoconstrictors.

14. Which of the following statements is true?
    a. The mucin layer of tear film lowers the surface tension of the cornea.
    b. Ocular demulcents are effective in alleviating corneal edema.
    c. The prescription-only ocular lubricants have been proven to be much more effective than the OTC lubricants.
    d. The absence of water for just a few moments can lead to the onset of corneal deterioration.

15. The lay term "pink-eye" is most closely associated with which of the following conditions?
    a. Conjunctivitis.
    b. Iritis.
    c. Keritits.
    d. Uveitis.

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CONTINUING PHARMACEUTICAL EDUCATION
The Eye and Its Disorders

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Evaluation ☐ Excellent ☐ Good ☐ Fair ☐ Poor

How long did it take you to read the article and complete the exam? _____

LOCAL NEWS

Chapel Hill

Two men entered Glen Lennox Pharmacy, apparently with a key, after the store was closed, but fled when the pharmacist returned unexpectedly. The illegal entry occurred about 8:30 pm, Wednesday, October 31.

Burlington

A 17-year-old Burlington youth was arrested and charged with breaking into Adams-McAsher Drug Company on Sunday, April 13, 1986. The youth was also charged with possession of controlled substances with intent to sell. He reportedly took Valium and Dilaudid.

Gastonia

Rite Aid Pharmacy was robbed Monday, July 21, 1986, by a knife-wielding man in his mid-20s who put a knife to a clerk's throat and demanded drugs. The robber received Valium, Percodan and Demerol. He fled on foot. The robber was described as large with red and green tattoos all over his arms and legs.

Greensboro

Hillsdale Park Drug Store was robbed of drugs and cash on Tuesday, July 22, 1986. The robber claimed to have a gun in a white paper bag he was carrying and demanded Demerol and Dilaudid from the pharmacist, as well as money from the cash register.

Statesville

Family Pharmacy was robbed Monday night, August 4, 1986 by an armed bandit who entered the store about 8:00 pm, pointed his revolver at the pharmacist and demanded drugs. The man left the store and fled the area on foot.

Fayetteville

A former Fayetteville policeman pled guilty to breaking and entering several area pharmacies and stealing assorted merchandise, cash and drugs. The break-ins were: Professional Drug Company, March 27; College Discount Drugs, May 1, July 21 and August 24; and the Medicine Shoppe on August 14, 1986.

NORTHWEST PHARMACISTS ASSOCIATION

The Northwest Pharmacists Association (NPA) completed its first full year of operation on June 30, 1986. The NPA represents approximately 125 pharmacists from a five-county area — Forsyth, Davidson, Davie, Stokes, and Yadkin.

During the 1985–86 year, the NPA offered its members 8 programs, with a total of 12 CE credits, at no charge. The Association also presented numerous educational programs to the community during Pharmacy Week, and established an Interprofessional Committee with the local medical and dental societies.

New Officers were installed at the July, 1986 meeting and include: President, Laura McLeod; First Vice President, Lori Tutterow; Second Vice President, Janet Foster; Secretary, Margaret LeDoux; Treasurer, Martha Southern; Executive Committee members Susan Claytor, David Cox, Kathy D'Achille, John Setzer, and Bill Simmons. We look forward to an equally successful second year.

Respectfully submitted, Kathy D'Achille, Past President.

CHARLOTTE WOMAN'S PHARMACEUTICAL AUXILIARY

After a three months "vacation" from meetings the Charlotte Woman's Pharmaceutical Auxiliary met in September with new officers in charge and meeting in a different place.

The Auxiliary has selected the Elk's Lodge and Club on Arrowood Road as the place for its Luncheon Meetings in the coming months.

Mrs. Johnie W. (Marguerite) Bennick, First Vice President and Program Chair presented Mr. John Rossier, former Chief Pharmacist at Presbyterian Hospital. Mr. Rossier gave an informative and interesting talk on "Patient Compliances with Drugs".

October Meeting of Auxiliary

The October Meeting of the Charlotte Woman's Pharmaceutical Auxiliary was held at the Elk's Lodge and Club. The President, Mrs. Leslie H. (Mary Lou) Davis gave an interesting

devotional entitled "Watering". This was very appropriate for the program that was to follow.

The First Vice President and Program Chair, Mrs. Johnie W. (Marguerite) introduced Mrs. Harold Bursley who presented a film and talk on famous "Wing Haven" — the Bird Sanctuary developed over the years, since September 1927, by Edwin O. and Elizabeth Clarkson. Wing Haven is open to the public at specified days and hours. However, tour groups and school children's groups can call to make appointments for tours.

A Wing Haven Foundation has been set up to preserve and oversee this Bird Sanctuary — and to make the arrangements for tours.

Wing Haven began as a formal garden but found that informal is much better for birds thus it has grown more informally as a truly sanctuary for birds.

The Herb Garden is different and most interesting. It would be especially interesting to people connected with Pharmacy.

LOCAL PHARMACIST WINS SCHERING SWEEPSTAKES FOR TRIP TO LONDON

John Welborn, part-owner of Lexington Drug #2 in Lexington, North Carolina, will join 49 other pharmacists and their guests on a week-long trip to London in November for winning a sweepstakes promotion sponsored by Schering Corporation. Welborn is the second pharmacist in North Carolina to win this sweepstakes.

To become a winner, Welborn, a pharmacist for 36 years, correctly answered the question, "What allergy remedy do most pharmacists recommend?" which was posed to him by an unidentified bonded security agent acting as a customer. The correct answer, "Chlor-Timeton," based on a recent survey of American pharmacists, is one of Schering Corporation's leading over-the-counter medications.

WEDDINGS

Ginger Grace Golding and CHARLES ALLEN WILKINS, both of Chapel Hill, were married Saturday, October 11, 1986 in Duke University Chapel in Durham. The Rev. Ray Hamilton officiated.

The bride received a bachelor's degree in nursing from the University of North Carolina at Chapel Hill and was a member of Sigma Theta Tau nursing honor society. She is a registered nurse in the Pediatric intensive care unit at Duke University. The bridegroom is a graduate of the School of Pharmacy, UNC-CH and a member of

Continued on page 32

Left to right: Winn Muse, local Schering representative; John Welborne; Jim Willis, Schering District Manager.

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WEEKEND PHARMACY COVERAGE NEEDED: Granville Hospital, a 66-bed community hospital, requires Pharmacist coverage on Saturdays and Sundays. Maintain unit dose system and patient profiles. Contact Joe Earnhardt, Director of Pharmacy, Granville Hospital, College St. Extension, Oxford NC 27565. (919) 693-5115.

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WEDDINGS

Continued from page 31

Kappa Psi fraternity. He is a pharmacist for Eckerd's.

TONYA JEANETTE DANIEL of Rocky Mount and James Dean Lackey of Raleigh were married October 11 at Lakeside Baptist Church, Rocky Mount.

The bride and bridegroom are both graduates of the School of Pharmacy of the University of North Carolina at Chapel Hill and both are pharmacists at Kerr Drugs in Raleigh. They will live in Raleigh.

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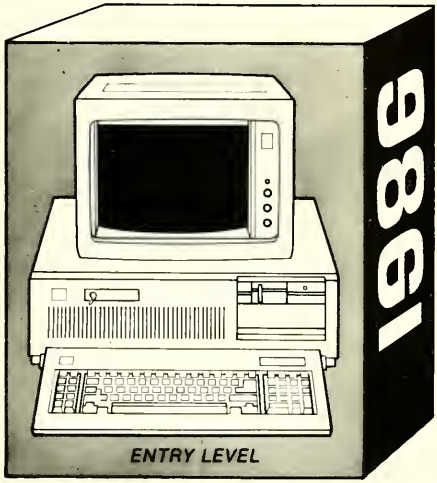

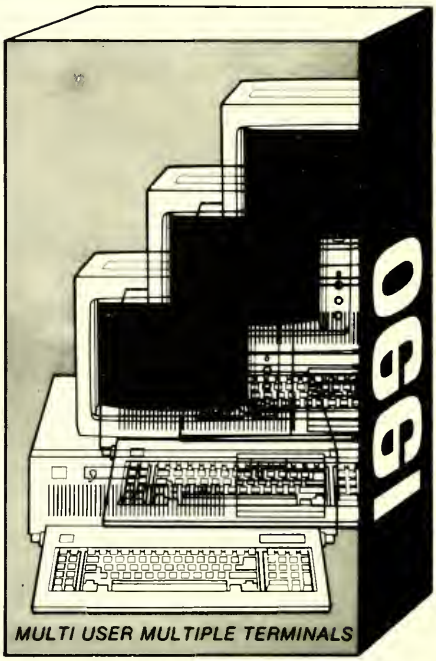

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Signs of the times

Remedies from the past Patterson's Mill Country Store

ELSIE BOOKER, PHARMACY HISTORIAN AND CURATOR

by Nancy Godbout

In a quiet, rural setting of North Carolina stands the Patterson's Mill Country Store, the dream come true for Mrs. Elsie Hudson Booker, pharmacist and member of the North Carolina Pharmaceutical Association. This combination country store and museum is located in southern Durham County on Farrington Road, actually just a few minutes from the bustle of busy Research Triangle Park.

People have traveled from all over the world to view her vintage pharmaceutical collection. Within two years of opening the museum on Thanksgiving Day in 1974, she had visitors from all 50 states and 15 nations sign her guest book. The drug companies in Research Triangle Park still make appointments to bring foreign guests for a tour of the museum.

For about fifteen years before the building of the store, which is located on Mrs. Booker's homestead, she gathered pieces to display. Her main interest has always been crude drugs and their history. During many years of relief work in area pharmacies she acquired pieces. In the less busy times in the stores, she would clean up in the pharmacies and box up no longer used containers and medications. The owners, having no further need for them, allowed Elsie to take them. Some of her pieces were found at flea markets.

Over the years, the manufacturers' representatives, knowing her interest, passed on information about stores that were soon to close. Antiques dealers told her about upcoming sales that contained items of interest. The massive breakfront for her pharmacy museum comes from Halifax, North Carolina. One piece she just barely missed out on became a part of the pharmacy at Disney World. People to this day still walk in with donations.

It also should be noted that the Patterson's Mill Country Store contains antique medical and dental items. Many of Elsie's medical items come from her uncle who had been in general practice in Burlington many years ago.

Elsie's collection is awe-inspiring. She has over 400 apothecary jars. About 200 of the oldest jars in her collection were acquired in Milwaukee. The museum is a work of love. She knows where each piece comes from. One cabinet contains items manufactured in Durham, Raleigh and Chapel Hill. The case next to it displays items manufactured within North Carolina. The majority of pieces date from 1880 to 1930.

Behind the counter amid her treasures

Besides the impressive container collection, one is overwhelmed with the assortment of signs for patent medicines. Her complete set of Dr. Pierce signs is the only one known of in the United States. Some of her duplicate signs were sold to the representatives of the Smithsonian Institute.

The people who visit Elsie's store and museum range from school children to senior citizens who come by the bus load. Some come to reminisce while others come to learn. The Smithsonian has identified Elsie's museum as one of two in the nation where visitors can walk through all parts of the pharmacy. Over the years she has scavenged the country for items. She knows exactly what she acquired in Sioux City, Natchez, and Hansville, Alabama.

Mrs. Booker's husband, John, also has a museum at the Patterson's Mill Country Store. He retired after 40 years with Ligget and Myers in Durham. His museum features tobacco advertising, logos and packaging. His collection is extensive and has been written up in US World Today. It was through his collecting that Elsie came into what she thinks could be one of a kind. On a trip to Chicago to view some tobacco items, John spoke about his wife's collection. As it

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ELSIE BOOKER

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turned out, he and their son, Curtis, arrived back home appropriately on a Mother's Day with 45 Parke-Davis crude drug cannisters. The date of manufacture is unknown, but there is no other collection as extensive as Elsie's, even at Parke-Davis.

Elsie Booker is as fascinating as her museum. She was the first pharmacist in her family. Her uncle, O. W. Hudson, had been a Bromo Seltzer salesman for many years. Her goal upon graduation was to get a retail job in Durham County. She had no desire to leave her family who had been on the homestead for over two hundred years.

In 1945, upon graduating from the University of North Carolina at Chapel Hill, she walked into the Durham Drug Company and asked Mr. Germain Bernard for a job. He told her to report on Monday. She responded by asking for a two week vacation prior to starting work. So two weeks later, she started her pharmacy career.

Mr. Bernard along with Mr. C. T. Council owned the BC Remedy Company. So when A. W. Clayton, pharmacist at the company needed help, it was Elsie who was sent over from the store to work as an analytic chemist. She was there when BC Remedy Company made its first tablet and when they took bromide out of the BC Powders.

In the late 40's and early 50's, she devoted herself to her family. She started working towards a teaching certificate, but about 1952 her husband asked her if pharmacy wasn't where she really belonged. That was enough for her to put the books away.

She started working at Eckerd's on Main Street in Durham and helped them set up the second and third Eckerd stores, Forest Hills and Broad Street respectively. She worked at T. E. Holden Drug Store in Hillsborough and retired from Kerr's Drug Store, Northgate, in the spring of 1973.

Elsie, who maintains her license, does not plan to return to retail pharmacy practice. The Patterson's Mill Country Store takes up much of her time and energy. She does admit that she would do it all over again, since it was through her profession that the pharmacy museum came about.

When asked, she will tell you that her most satisfying moment was when her museum received nationwide recognition. In August 1980, Elsie was awarded the Certificate of Commendation of the American Institute of the History of Pharmacy. The award is given to those who make significant and considerable contributions to the historical and cultural aspects of pharmacy.

Elsie has been a member of NCPhA since 1960. She is a member of the Durham Orange Pharmaceutical Association, having served as president and secretary. In 1968, she was named its Pharmacist of the Year. She is a charter member of the Alumni Association of the UNC School of Pharmacy. She is a member of Kappa Epsilon and the North Carolina Pharmaceutical Association Academy of Pharmacy.

The Patterson's Mill Country Store is open from 10:00 am to 5:30 pm, Monday through Saturday and from 2:00 pm to 5:30 pm on Sunday. It is well worth the trip to see the museum and to meet Elsie. On your way out the door, try the penny scales. Elsie brought them back from Hansville, Alabama, but that's another story itself.

Editor's note: Author Godbout, a graduate student in Pharmacy Practice at UNC, prepared this article while serving an internship at the office of the NCPhA.

Old Prescription Stock Bottles & Counter

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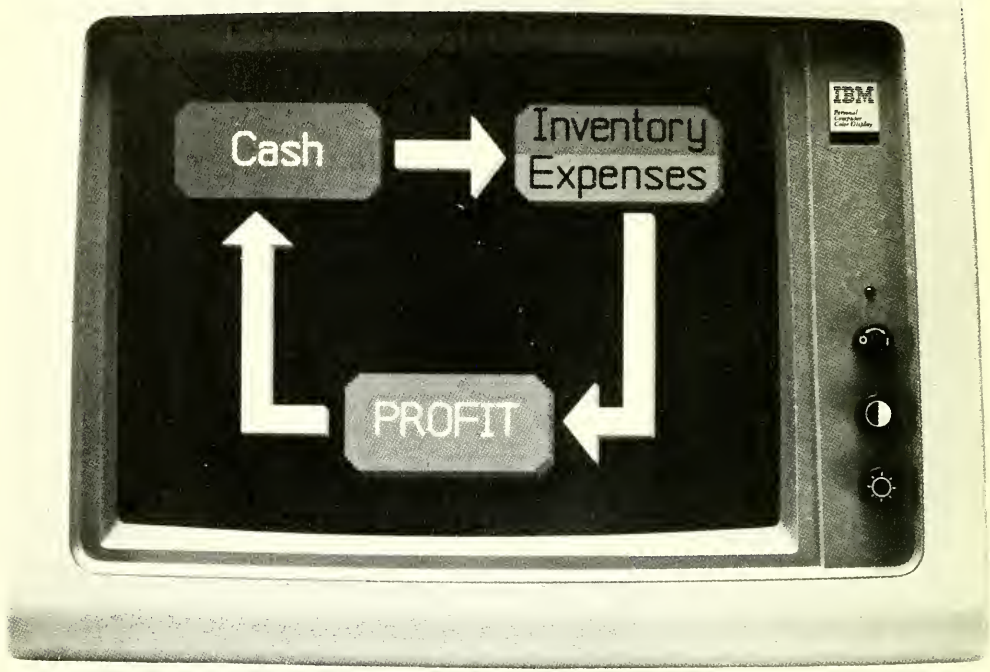

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COMMITTEE REPORT OF THE COMMITTEE ON COMMUNITY PHARMACY

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Liason to Executive Committee

REPORT OF THE COMMITTEE ON COMMUNITY PHARMACY

The committee met at 11:00 a.m. on Sunday, February 2, 1986, at the Institute of Pharmacy in Chapel Hill.

Topics of discussion were:

1. Price tier business
2. Samples
3. Doctors dispensing
4. Addresses, Names and DEA numbers on physician blanks
5. Third party plan reimbursements
6. Cost of filling
7. Mail order prescriptions
8. Pharmacy network
9. Former legend drugs

On behalf of the committee:
Ed Howard, Chairman

RESOLUTION

Repeal of Modification of the Non-Profit Institutions Act Exemption in the Robinson-Patman Act

Introduced by the Committee on Community Pharmacy

Whereas,

Commercial non-profit institutions, including hospitals and health maintenance organizations (HMOs), are obtaining prescription drug products at discriminatory prices and selling them in competition with "for profit" pharmacies, and

Whereas,

Such discriminatory sales and resales by commercial "non-profits" was never contemplated by Congress in passing an exemption for charitable institutions from the Robinson-Patman Act in 1938, and

Whereas,

Said commercial "non-profit" institutions are receiving substantial tax relief and other economic benefits which further subsidize their competition with "for-profit" pharmacies, therefore

Be it resolved that the North Carolina Pharmaceutical Association seek and support the repeal or modification of the Non-Profit Institutions Act exemption from the Robinson-Patman Act, and any other legislative changes as are necessary to restore fair competition to the prescription drug market place.

RESOLUTION

Contribution to Safety, Care, Welfare and Cost Containment of Pharmacy Patients

Introduced by the Committee on Community Pharmacy

Whereas,

This Committee recognizes the fact that many areas of our practice could be improved which

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ANNUAL CONVENTION

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would benefit the public health, safety and welfare, and

Whereas,

The following recommendations would accomplish this goal, therefore

Be it resolved

1. The distribution of prescription drug samples by manufacturers or their representatives cease,
2. Dispensing of prescriptions by non-pharmacists be under direct supervision of a pharmacist in a pharmacy,
3. That the NCPhA urge the NC Board of Pharmacy to join efforts with all other state boards of pharmacy to closely supervise or eliminate the mailing of prescriptions across state lines where no pharmacist-patient relationship exists,
4. That legend drugs becoming Over The Counter (OTC) drugs be sold only in a pharmacy by a pharmacist for at least the first year after conversion,
5. That a survey be conducted by the NCPhA of at least one hundred pharmacies (or a statistically accurate sample) to determine the cost of dispensing a prescription in North Carolina, and

Be it further resolved that these measures be considered wholely or individually to lead to containment of health care costs, safety and the general health of pharmacy patients in North Carolina.

SURPRISING FACTS ABOUT CARDS

The average adult buys about 30 cards a year.

Greeting cards account for 50% of all personal mail sent from household to household. Retail card sales are about $3.2 billion and seven billion cards annually. Chain and independent drug stores now have about 23% of the market, up 50% in the past three years. This trend will continue,

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SIGNIFICANT GAINS AGAINST CARDIOVASCULAR DISEASE REDUCE PRIME KILLER IN INDUSTRIALIZED NATIONS

Jim Fixx, the late author and jogging advocate, died of a massive heart attack while running. Several of his relatives reported that he had ignored certain signs of trouble — shortness of breath, pain in the middle of the chest.

How many others are ignoring similar warning signs? And what are the consequences?

Statistics show that 20 percent of all cardiovascular disease-related deaths are due to sudden cardiac death. In some cases, there are no warning signs at all.

The American Heart Association predicts that 1.5 million Americans will suffer heart attacks this year. Nearly a third will die.

The Alarming Statistics

Heart attack and stroke remain the leading causes of death in the United States and other industrialized nations. In 1984, 48 percent of all deaths in the U.S. were caused by cardiovascular disease. In a survey of European industrialized nations, deaths from cardiovascular disease accounted for 21 to 40 percent of all fatalities.

While the highest mortality rate occur in people more than 74 years old, some 10 million Americans younger than age 65 have signs of cardiovascular disease. And within the latter group, there are some revealing distinctions according to sex and race. Fifty-seven million people have high blood pressure, a known factor contributing to cardiovascular problems. Men under age 65 suffer from heart disease more than twice as often as women of similar age. And black men are at greater risk to develop cardiovascular disease than white men, probably because of a higher incidence of hypertension among blacks.

Economic Costs of Cardiovascular Disease

Cardiovascular disease constitutes the costliest of all disease groups — $78 billion in the U.S. in 1985. That figure includes medical care costs, lost potential earnings due to premature death or disability, and benefits paid. Atherosclerotic heart disease tops the list as the most prevalent and costly of cardiovascular diseases.

What Are the Major Risk Factors?

Atherosclerosis — the narrowing of blood vessels caused by the formation of yellowish plaques of cholesterol as well as other lipids (fatty substances) and cellular debris — is the primary cause of arterial disease. The narrowing caused by these deposits results in reduced blood flow to the vital organs and other tissues. What can follow is an inadequate oxygen supply to these tissues, resulting in tissue death and organ failure.

Scientists have identified some key factors that increase the risk of atherosclerotic heart disease and stroke. Some are beyond the control of the individual, among them:

- Heredity
- Gender
- Race
- Age

Other risk factors may be controlled, including:

- Obesity
- High blood cholesterol levels
- High blood pressure
- Lack of exercise
- Stress
- Diabetes
- Smoking

Smokers are more than twice as likely to suffer a heart attack than nonsmokers, and two to four times more likely to die from it. When a one pack-a-day person stops smoking, it takes an average of ten years to achieve the risk odds of a nonsmoker.

Diet and Cardiovascular Disease: The Salt and Fat Connection

According to the American Heart Association the average American eats too much saturated fat and salt. Excess cholesterol in the diet can result in a buildup of fatty deposits on the inner walls of blood vessels. The AHA recommends blood cholesterol levels be maintained below 200 milligrams per deciliter (mg/dl). Lack of exercise and excess weight contribute to elevated levels of cholesterol.

"Half of all people in the U.S. who have heart attacks have cholesterol values between 200 to 250 mg/dl," says William P. Castelli, M.D., director of the Framingham (Mass.) Heart Study, a 36-year study following an original 5,100 men and women for evidence of cardiovascular

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CARDIOVASCULAR DISEASE

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disease. "These are people who thought they didn't have a cholesterol problem. The average man who has a heart attack in this country has a total cholesterol value of 244."

"All people should strive to get their cholesterol levels below 200 mg/dl — levels which are achieved in three-fourths of the world where heart disease is uncommon, such as Asia, Africa and South America," Dr. Castelli says. "On these continents, the average cholesterol level is 160 mg/dl."

In addition, excessive amounts of *low density lipoprotein* cholesterol (LDLs) — which transport most of the cholesterol in the bloodstream — and highly saturated (hydrogenated) fats predispose individuals to heart disease. On the other hand, not all lipids are unhealthy. Certain types even seem to have a protective effect against atherosclerosis. *High density lipoprotein* cholesterol (HDLs) which transport some of the body's serum cholesterol, and unsaturated (non-hydrogenated) fats inhibit the formation of plaque inside blood vessels. HDLs transport saturated fat to the liver to be broken down and discarded. Physical activity elevates the HDL fraction. Active men with elevated HDL fractions have a correspondingly lower incidence of heart disease than inactive men with lower HDL levels. Results from the Framingham study indicate that heart disease is more likely to develop when the ratio of total cholesterol to HDL is high.

Much of our processed food contains huge amounts of sodium (salt). Excess sodium causes water retention and may increase blood pressure. The average American consumes 8 to 10 grams of sodium each day.

"Unfortunately, we do not yet have an easy way to differentiate salt-sensitive from salt-resistant individuals," says Robert I. Levy, M.D., professor of medicine at Columbia University College of Physicians and Surgeons in New York City.

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(l-r: Cynthia Norman, Hugh Chatham Memorial Hospital; Dr.Joseph E. Walker, Ram Air; Gordon G. Hamrick, Kendall Drug Co.)

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The actual need for sodium is very low — under ½ gram daily — and the AHA recommends that the general population restrict dietary sodium.

In order to maintain a low-sodium diet, people must become familiar with the sodium content of everyday foods. For example, a lunch consisting of a ham sandwich, a pickle and a bowl of canned soup would already exceed a sodium restriction of two grams per day.

"In populations where a low-salt diet is the norm (in regions of Africa and South America)," Dr. Levy adds, "there is a very low incidence of hypertension. Conversely, in countries such as Japan and Korea, where salt consumption is high, hypertension is rampant."

High Blood Pressure: The Silent Killer

Hypertension, or high blood pressure, unchecked over a prolonged period damages blood vessels, overworks the heart and leaves the victim vulnerable to stroke, heart attack, kidney disease and other illnesses.

The increased strain on blood vessels even in mild hypertension may result in accelerated atherosclerosis and coronary heart disease.

Stress and the Hot Reactor

Emotional stress may be a contributing risk factor in heart disease. While all of us deal with some degree of tension in our lives, some people do not tolerate it well. Hard-driving, time-pressured "workaholics" appear to have an increased risk of developing cardiovascular disease.

The bodies of other at-risk individuals may over-react physically to mildly stressful situations and pour out adrenalin and other hormones that trigger a surge in blood pressure. These people, so-called "hot reactors," may be in particular danger of developing cardiovascular disease unless they learn to lessen this response through stress modification such as biofeedback or relation-response techniques.

Some experts believe that coronary artery spasm — constriction of blood vessels in the heart — can be induced by tension. Such spasm, even in the absence of advanced atherosclerosis, can result in a *myocardial infarction* (heart attack). Tension may produce vasospasm which can damage arterial walls and produce a *thrombus* (a localized blood clot) resulting in a heart attack. Reduced blood flow and the release of vasoconstrictive chemicals may cause further coronary artery spasm. Death of the heart muscle areas fed by the blocked coronary artery ensues.

D-i-a-b-e-t-e-s Spells Danger

Men and women with diabetes are more prone to develop cardiovascular and kidney disease than those without it, possible because diabetes is associated with hypertension, increased atherosclerosis and elevated blood lipids. For them, proper weight and blood sugar control through low-fat, low-sugar diets and a routine of regular exercise often helps prevent dangerous complications.

Curiosities or Contributing Factors? Bacterial/Viral Infections and Sleep Apnea

Can bacterial and viral infection cause cardiovascular disease? In some cases, the answer is clear, in others it's not so apparent. Infective endocarditis, a bacterial infection of the heart, may occur following a dental or other surgical procedure in which an open wound allows excess bacteria into the bloodstream. Dentists, however, generally prescribe preventive treatment with an antibiotic after such procedures, particularly for patients with known heart disease or heart valve defects.

Strep throat may also develop into rheumatic fever, which can cause inflammation and permanent damage to the heart.

Researchers have discovered herpes virus in diseased human arteries. These scientists are investigating whether the herpes virus family may be the long-sought triggers to the plaque buildup that results in atherosclerosis.

Do breathing problems in sleep produce cardiovascular disorders? Overweight men, particularly older men who snore heavily, may be suffering from a breathing disorder known as *sleep apnea.* The condition is characterized by long breathing lapses and gasping for breath during sleep. The result — a lack of oxygen — is linked to high blood pressure and overexertion of the heart. Clinicians studying *sleep apnea* speculate that it could be related to higher mortality rates in men.

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CARDIOVASCULAR DISEASE

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Whole Body Perspective: Peripheral Vascular Disease and Stroke

An ailment known as peripheral vascular disease refers to any blood vessel obstruction in the extremities. Depending on the degree of obstruction, pain, inability to walk, infection and amputation may result.

Arteriosus obliterans, or the complete blockage of an artery in the leg, is the most severe and common form of peripheral vascular disease.

A *stroke* develops when the blood supply to the brain is disrupted. This can be caused by a cerebral artery occlusion (blockage) due to a clot or hemorrhage. Irreversible brain cell death results when blood and oxygen supplies are disrupted for more than a few minutes. The portion of the brain affected and the size of the infarction (cell death) determine the degree of neurological damage.

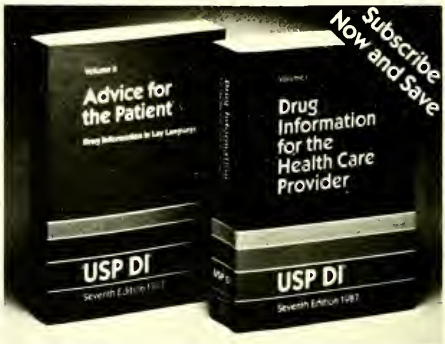
High blood pressure is a primary risk factor in determining vulnerability to stroke. Additional pressure exerted on weakened arteries may cause an *aneurysm* (bubble) to form along a portion of the artery wall. Surges of pressure may subsequently force a cerebral aneurysm to burst. Surviving this type of *hemorrhagic stroke* is unlikely.

A blood clot resulting in a stroke may originate in a narrowed cerebral artery, or may be a fragment from a peripheral artery that breaks loose and lodges in a cerebral artery (embolism).

Accelerating Progress

The last several decades have been marked by significant strides against cardiovascular disease, including:

- Greater knowledge as to how diet influences the development of cardiovascular disease (hypertension, high cholesterol).
- Findings conclusively linking smoking and heart disease.
- Sensitive diagnostic techniques that can more accurately diagnose problems early (echocardiography, nuclear imaging).
- Specific cardiovascular drugs (including the newer selective beta blockers, calcium channel blockers, ACE inhibitors and clot-specific anticoagulants) that improve medical treatment of heart disease.



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RUSTY HAMRICK ELECTED PRESIDENT OF KENDALL DRUG COMPANY

At the annual September board meeting of Kendall Drug Company, C. Rush Hamrick, III was elected to the office of president. He succeeds his father, C. Rush Hamrick, Jr., who is retiring from the company after 40 years of service, having been president since 1964. He succeeded his father, the late C. Rush Hamrick, Sr. Gordon Grice Hamrick was elected chairman of the board.

Other officers include Dale Rutledge Hamrick, operations manager, John Wortman, purchasing manager, Myra McGinnis, data processing manager, Betsy Fonvielle, comptroller and Bobby McDaniel, sales manager.

One of the few remaining family-owned wholesale drug houses in the country, the business had its beginning in 1896 when Henry E. Kendall opened a drug store at the corner site of A. V. Wray and 6 sons on the court square. A pharmacist, he mixed some of his own formulas and became so well-known he eventually began to dispense to other nearby drug store and hospitals on a wholesale basis.

Rush, Sr. became associated with the business in 1922 and a year later bought controlling interest in the firm and converted it to a wholesale house. Through the years the Hamricks bought all outstanding stock until it became totally owned by the family. In 1960 the name was changed from Kendall Medicine Company to Kendall Drug Company.

The wholesale firm serves drug stores, hospitals and other health related institutions over a 20-county area in western North Carolina and also handles contracts with other hospitals and health institutions over the state.

C. Rush Hamrick, III is a graduate of Shelby High School and earned a B.S. Degree in Business Administration from UNC-CH. He joined Kendall in 1973 after three-years with the U.S. Navy as a Lieutenant (jg). He is the father of two sons, Charles Rush Hamrick IV and George Blanton Hamrick. He has been active in local civic affairs and at Shelby Presbyterian Church where he is an elder.

C. Rush (Rusty) Hamrick, III

Gordon Hamrick, chairman, formerly treasurer and vice-president, joined the company in 1960. He is a UNC-CH graduate with a degree in Business Administration. Upon graduation, he joined Proctor & Gamble in a management capacity for four and half years before returning to Kendall Drug to work with his father and brother.

The company honored the retired president and his wife at a reception at the Hamrick Center on October 27.

SURPRISING FACTS

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with 20% annual growth predicted over the next few years.

Card retails range from $.35 to $7.50, with the average price at about $1.

Women buy 90% of all greeting cards. Half the cards purchased are seasonal and the rest every day; nonoccasion card sales are on the rise. The most popular card-sending holidays are, in order, Christmas, Valentine's Day, Easter, Mother's Day, Father's Day and Graduation.

WOMAN'S AUXILIARY FALL CONVOCATION

The Fall Convocation was held Wednesday, October 15, 1986 at the Institute of Pharmacy in Chapel Hill. Registration and coffee started at 9:30 am. The Hospitality Committee did a great job. The food was delicious and the pumpkins and autumn leaves added a nice touch. I would like to thank the following women: Mrs. Rose Boyd, Chairman, Kenly; Mrs. Ruby Creech, Mrs. Vivia Creech, and Mrs. Sarah Ann Sasser, Smithfield; Mrs. Dollie Corwin, Charlotte; Mrs. Jeanie Wilson, Raleigh; Mrs. Anne Woodard, Princeton.

Our business session began at 10:00 am. Mrs. Ruby Creech gave our Welcome and Mrs. Mary Good gave the Invocation. Mr. A.H. Mebane, III, NCPhA Executive Director, introduced our special guests. Dean Tom Miya brought news from the UNC School of Pharmacy and Mrs. Lib Fearing gave us a message from her husband Keith, President of the NCPhA who could not be with us.

Mr. J. L. Brooks, State Director of Chapter Development for Mission Air, informed us of the history of Mission Air and their aid to families. Mr. Donald R. Simpson, President/Director of Mission Air assisted Mr. Brooks in the presentation.

Mission Air founded in 1981, is a non-profit organization dedicated to serving people in need by sharing the love of Jesus Christ through benevolent air transportation of the ill, or injured to major medical centers, burn units, children's hospitals, rehabilitation centers and organ transplant units. Mission Air provides —

Personal transportation of family members during prolonged periods of serious illness or because of accident, death or visits to prisons or rehabilitation centers.

Emergency transportation related to a specific need for a particular blood type, serum, organ, food, medicine, or supplies.

Disaster transportation for special missions into depressed areas, following natural disasters, or for search and rescue missions.

Special transportation assistance to other ministries in their work for drug rehabilitation, alcoholism, and child abuse.

Each mission is individually evaluated and every effort is made to fill the need of those who desperately need air ambulance transportation but otherwise cannot obtain or afford it. Since 1983, Mission Air has flown more than 340 missions, 176 missions in 1985 alone.

Mission Air is supported by contributions and donations from individuals, corporations, civic groups, churches, grants, foundations; and has several annual fundraising projects, i.e., a golf

"White Elephant" Bag Sale Treasures are examined

tournament, an open house, and an annual dinner.

A check for $500 was presented to Mission Air from the Woman's Auxiliary.

This was followed by the "White Elephant" Sale. Each woman brought a decorated paper bag containing a "white elephant" to be sold — $138 was raised. A prize was awarded to Mrs. Ruby Creech for the most originally decorated bag — a Jack-O-Lantern made from paper napkins and construction paper.

Our next guest speaker was Dr. Diane Gwinn Schaaf, a clinical psychologist with her own private practice located in Chapel Hill. She gave a most interesting and informative talk entitled "Living with Oneself and One's Family."

We adjourned to a delicious lunch catered by Baxley's of Raleigh.

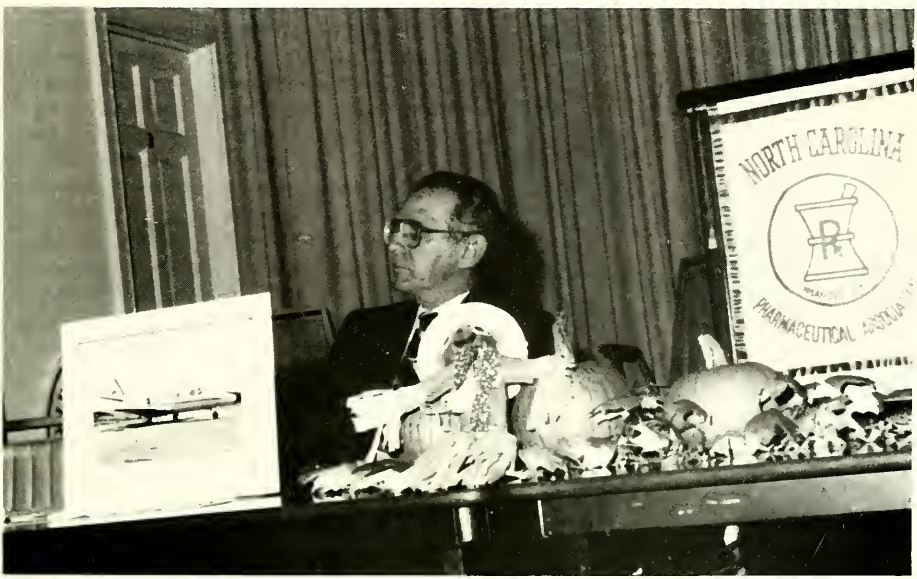
Jewell H. Oxendine, President

Hedy E. House, 1976 UNC School of Pharmacy graduate, participated in a symposium at Bennett College, Greensboro, on "Career Options for Women in Medical Fields." The symposium was held November 11, 1986 at the Henry Pfeiffer Science Building on the campus of Bennett College

DEDUCTING YOUR PROFESSIONAL DUES

The new tax bill will limit miscellaneous deductions (which include nonreimbursed employee business expenses) to that amount that exceeds two percent of adjusted gross income, beginning with the 1987 tax year. This change may effectively eliminate the deduction for professional dues for most employee pharmacists. This does not mean professional dues will no longer be deductible per se; for itemizers, this expense will be included to calculate total miscellaneous deductions, which is deductible to the extent it exceeds two percent adjusted gross income.

Several professional associations are recommending that members prepay future years' dues now and take the deduction on their 1986 returns. Not even the IRS can say how it may rule on this; the most important consideration will be the "facts and circumstances" of each case. "Facts and circumstances" that look more like tax avoidance than legitimate business purpose may result in an unfavorable ruling.



Convocation speaker, Mr. J.L. Brooks, Mission Air.

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Continued from page 19

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1987 Session Nears HOW TO WRITE YOUR LEGISLATOR

In this day and age of "instant" communications, the *letter* still carries a lot of weight with your legislator. Whether the legislator is in Washington or Raleigh, the style and thrust of your letter should be the same. It is not a difficult task to write them, but here are a few guidelines to help you along.

1. Always use your personal or business letterhead and sign your name over the typed signature at the end of the letter.

2. Be sure your exact address is on the letter, not just the envelope. Envelopes get thrown away before the letter is answered.

3. Identify the subject clearly. State the name of the legislation you are writing about. (Give the bill number if possible.)

4. State your personal reason for writing. Your personal experience is your best supporting evidence. Explain how the issue will affect you and your patients.

5. Avoid stereotyped phrases and sentences that give the appearance of a form letter. They identify your letter as part of a "pressure campaign" and loses its impact.

6. Be reasonable, don't ask for miracles. Don't threaten and don't say "I'll never vote for you if you do so and so."

7. Ask the representative to give you his or her position on the issue in a reply. As a constituent you are entitled to know.

8. Stay on top of legislation and write your letters early. The later you wait, the more likely the legislator is to have made a commitment that he can't change.

Above all, be positive. Thank your legislator for their past support or hand work. Everybody appreciates a compliment and politicians are no different. On the other hand, if they vote against your position you need to tell them, in a diplomatic way. Your legislators need your input and pharmacy needs your support.

WORK MAKES PRESENTATION AT NABP MEETING

NC Board of Pharmacy Executive Director David R. Work presented a model veterinary drug code at the National Association of Boards of Pharmacy Executive Committee meeting in Monteray, California, in early November. Work is the NABP representative to the Food and Drug Administration and the Association of Food and Drug Officials. He suggested that many states are lacking in this type legislation and each state should review and consider enacting laws regulating these drugs.

DICKINSON'S PHARMACY

by Jim Dickinson

On the hot seat! Back in ancient times, when I first strayed into pharmacy from the world of big city journalism, my "preceptors" cautioned me about many things. One was the habit many pharmacists had of "hiding" away from customers and visitors, deeply engrossed in their pharmacy.

The "box syndrome," as one highly successful pharmacist diagnosed the condition of his colleagues, a little scornfully. "They have a limited view of the world, and their business —everything they see is framed by the view they get from behind the counter."

It's been nearly 15 years since he shared that wisdom with me, but I still haven't decided yet whether he was being fair to his profession, or just diagnosing a minority of pharmacists.

However many of them there are out there —pharmacists who "hide" and don't want to get involved — I believe they're in for an uncomfortable time, because their activist colleagues are putting all pharmacists "on the hot seat," one way or another.

Probably, it's going to get a lot hotter, yet. Consider the evidence.

- *The aging of America.* Now no longer deniable, this historic change in our makeup is bringing with it a host of new ideas, scams and pressures, converging on the pharmacy. For example, most of the big-market drugs now target older people, who for the first time are the most-affluent and best-informed people we have — and they're the ones who want to second-guess the prescriber. That equals questions for pharmacists. Also, the new products bring new claims, and direct-to-consumer advertising. That equals questions for pharmacists. And there's a whole raft of "fountain-of-youth" products pouring out of the hopper for older folks. That equals questions for pharmacists.
- *Liability/malpractice.* While legislators everywhere are scrambling to bring a little sanity to this ridiculous situation, relief isn't yet in sight for prescribers, HMOs and hospitals. Courts thus far are staunchly refusing to place new burdens on pharmacists in this area. That equals more customers for pharmacies — and more questions! — as self-care increases somewhat in proportion to the increase in physician/institution overheads.
- *Alternative care settings.* These are already proliferating, in the form of "wellness programs," mail-order prescriptions, self-care, dispensing physicians, prescribing physician-assistants and nurses, home care and HMOs. That equals more competition — and more questions! — for pharmacists.
- *More regulation.* The drug diversion scandal is a sign of things to come. As shortcuts and scams increase, the pressure on states to regulate what they don't already regulate can only increase. That equals more intrusions for pharmacists to resist. Already, the pharmaceutical industry is mounting its most costly lobbying efforts at the state level, and the focus of the major national pharmacy associations has been shifting to the states for years, offering state associations a networking dimension they haven't needed before but need now. That equals more calls on pharmacists to "get involved."

These and other indicators of change are crowding in on more and more pharmacists.

For many years, I've noticed an increasing tendency for FDA leaders to mention pharmacists in their strategy talks, and when they seem to be thinking-out-loud. They see pharmacists as an untapped health resource. I've also noticed the ranks of FDAers swelling with pharmacists, and now there are so many they have their own association, and are talking about expanding it to embrace pharmacists engaged in government work at state and local levels, as well — "the American Society of Regulatory Pharmacists."

Plan for the future? What'll things be like in the 21st century? Pharmacy's in the hot seat *now!*

What to do about it? First, pharmacists need to do what their associations have been urging them to do for years: Get involved! The world won't wait respectfully outside your doors forever.

JOIN your local PSAO and PPO. GIVE to state and national PACs. WRITE your representatives and the media about the insurance, Medicaid reimbursement, syrup of ipecac, drug diversion, OTC drug tampering and other crises (don't know enough about them to write on them? — find out! Become an authority!) READ your state and national pharmacy publications. READ your local state and community news. READ. READ. READ.

Do pharmacists have the *inner fire* to seize the opportunities that are knocking? Or is yet another review of that "box" an easier approach?

Continued on page 23

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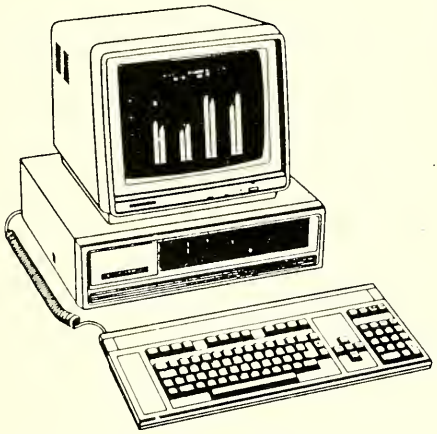

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DICKINSON'S PHARMACY

Continued from page 21

Want to know what I think? I think that through networking, through student motivation, through mere observation of the obvious opportunities all around, through keeping tuned-in, through *doing* rather than talking, and, yes, through risk-taking, a growing number of pharmacists are taking charge right at this very moment.

They're already on the "hot seat," and the future belongs to them.

This feature is presented on a grant from G.D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G.D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G.D. Searle & Co.

LETTERS TO THE EDITOR

Each year as part of the Introduction to Pharmacy course, I assign each pharmacy student to do a pharmacy practice report. This involves visiting a pharmacy operation and interviewing a pharmacist. This project continues to be a very successful one because of the fine support we receive from North Carolina pharmacists. Since it is difficult for me to thank each individual pharmacist personally for the time he or she makes available to our students, I wanted to use this letter to thank you all collectively. North Carolinians are special people. North Carolina pharmacists uphold this image. Our School and students are very fortunate to have the type of cooperation we receive from you. Thank you on behalf of the pharmacy students for your continuing support.

Sincerely,

Fred M. Eckel, M.S.
Professor of Hospital Pharmacy and
Chairman, Division of Pharmacy Practice

RESOLUTIONS FOR THE 1987 CONVENTION

As Chairman of the Committee on Resolutions for the 1987 Convention I feel a responsibility to communicate with you at this early date for several reasons. First of all I believe it is a wise procedure to give careful thought to any and all resolutions which might be proposed. Secondly, in the past there has been some problems with resolutions not being available in printed form for the delegates at the Convention to review. And thirdly, the Resolutions Committee needs a sufficient amount of time prior to the Convention to consider proposed resolutions.

Accordingly, I have set a deadline for submission of all resolutions to the Resolutions Committee of March 25, 1987. Please have any resolutions which you wish to have presented to the Convention sent to me at the address on this letterhead prior to March 25th. The Resolutions Committee will meet between that time and the first day of the Convention to place each resolution in proper form and have them available for the delegates. I appreciate your cooperation in this effort.

David R. Work, Chairman
NCPhA Resolutions Committee
P.O. Box H
Carrboro NC 27510

GERIATRIC UPDATE

"Geriatric Drug Update — 1987", sponsored by the National Institute on Aging, Food and Drug Administration, Office of Disease Prevention and Health Promotion, and Administration on Aging, will be held at the National Institutes of Health in Bethesda, Maryland, on May 4–5, 1987. The meeting has no registration fee, but advance registration is requested to insure seating. Topics to be discussed include: generic drug substitution (including clinical, regulatory, and economic issues), health fraud, drug testing in the elderly, geriatric food/drug interactions, drug utilization and adverse reaction surveillance, geriatric drug education and training for health professionals, therapeutic innovations, biopharmaceutics innovations and problems, health behavior and patient education, health promotion and evaluation, and future directions. Continuing education certification will be provided to physicians, pharmacists, and nurses. Further information, including a preliminary program and registration material can be obtained by writing: Steve Moore, National Institute on Aging, Building 31, Room 5C-05, National Institutes of Health, Bethesda, MD 20892.

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Brief Summary

NEW...ONCE DAILY IN MILD TO MODERATE HYPERTENSION

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CONTRAINDICATIONS: 1) Severe left ventricular dysfunction (see WARNINGS), 2) Hypotension (less than 90 mmHg systolic pressure) or cardiogenic shock, 3) Sick sinus syndrome or 2nd or 3rd degree AV block (except in patients with a functioning artificial ventricular pacemaker).

WARNINGS: Heart Failure: ISOPTIN should be avoided in patients with severe left ventricular dysfunction (see DRUG INTERACTIONS). Patients with milder ventricular dysfunction should, if possible, be controlled before verapamil treatment. Hypotension: ISOPTIN (verapamil HCl) may produce occasional symptomatic hypotension. Elevated Liver Enzymes: Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Periodic monitoring of liver function in patients receiving verapamil is therefore prudent. Accessory Bypass Tract (Wolff-Parkinson-White): Patients with paroxysmal and/or chronic atrial flutter or atrial fibrillation and a coexisting accessory AV pathway have developed increased antegrade conduction across the accessory pathway producing a very rapid ventricular response or ventricular fibrillation after receiving intravenous verapamil. While this has not been reported with oral verapamil, it should be considered a potential risk. Treatment is usually D.C.-cardioversion. Atrioventricular Block: The effect of verapamil on AV conduction and the SA node may cause asymptomatic 1st degree AV block and transient bradycardia. Higher degrees of AV block, while infrequent (0.8%), may require a reduction in dosage or, in rare instances, discontinuation of verapamil HCl. Patients with Hypertrophic Cardiomyopathy (IHSS): Although verapamil has been used in the therapy of patients with IHSS, severe cardiovascular decompensation and death have been noted in this patient population.

PRECAUTIONS: Impaired Hepatic or Renal Function: Verapamil is highly metabolized by the liver with about 70% of an administered dose excreted in the urine. In patients with impaired hepatic or renal function verapamil should be administered cautiously and the patients monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacological effects (see OVERDOSAGE).

Drug Interactions: Beta Blockers: Concomitant use of ISOPTIN and oral beta-adrenergic blocking agents may be beneficial in certain patients with chronic stable angina or hypertension, but available information is not sufficient to predict with confidence the effects of concurrent treatment in patients with left ventricular dysfunction or cardiac conduction abnormalities. Digitalis: Clinical use of verapamil in digitalized patients has shown the combination to be well tolerated if digoxin doses are properly adjusted. However, chronic verapamil treatment increases serum digoxin levels by 50 to 75% during the first week of therapy and this can result in digitalis toxicity. Upon discontinuation of ISOPTIN (verapamil HCl), the patient should be reassessed to avoid underdigitalization. Antihypertensive Agents: Verapamil administered concomitantly with oral antihypertensive agents (e.g., vasodilators, angiotensin-converting enzyme inhibitors, diuretics, beta blockers, prazosin) will usually have an additive effect on lowering blood pressure. Patients receiving these combinations should be appropriately monitored. Disopyramide: Disopyramide should not be administered within 48 hours before or 24 hours after verapamil administration. Quinidine: In patients with hypertrophic cardiomyopathy (IHSS), concomitant use of verapamil and quinidine resulted in significant hypotension. There has been a report of increased quinidine levels during verapamil therapy. Nitrates: The pharmacologic profile of verapamil and nitrates as well as clinical experience suggest beneficial interactions. Cimetidine: Two clinical trials have shown a lack of significant verapamil interaction with cimetidine. A third study showed cimetidine reduced verapamil clearance and increased elimination to 1/2. Anesthetic Agents: Verapamil may potentiate the activity of neuromuscular blocking agents and inhalation anesthetics. Carbamazepine: Verapamil may increase carbamazepine concentrations during combined therapy. Rifampin: Therapy with rifampin may markedly reduce oral verapamil bioavailability. Lithium: Verapamil may lower lithium levels in patient on chronic oral lithium therapy. Carcinogenesis, Mutagenesis, Impairment of Fertility: There was no evidence of a carcinogenic potential of verapamil administered to rats for two years. Verapamil was not mutagenic in the Ames test. Studies in female rats did not show impaired fertility. Effects on male fertility have not been determined. Pregnancy (Category C): There are no adequate and well-controlled studies in pregnant women. ISOPTIN crosses the placental barrier and can be detected in umbilical vein blood at delivery. This drug should be used during pregnancy, labor, and delivery, only if clearly needed. Nursing Mothers: ISOPTIN is excreted in human milk, therefore, nursing should be discontinued while verapamil is administered. Pediatric Use: Safety and efficacy of ISOPTIN in children below the age of 18 years have not been established.

ADVERSE REACTIONS: Constipation 8.4%, dizziness 3.5%, nausea 2.7%, hypotension 2.5%, edema 2.1%, headache 1.9%, CHF/pulmonary edema 1.8%, fatigue 1.7%, bradycardia 1.4%, 3° AV block 0.8%, flushing 0.1%, elevated liver enzymes (see WARNINGS). The following reactions, reported in less than 1.0% of patients, occurred under conditions (open trials, marketing experience) where a causal relationship is uncertain; they are mentioned to alert the physician to a possible relationship: angina pectoris, arthralgia and rash, AV block, blurred vision, cerebrovascular accident, chest pain, claudication, confusion, diarrhea, dry mouth, dyspnea, ecchymosis or bruising, equilibrium disorders, exanthema, gastrointestinal distress, gingival hyperplasia, gynecomastia, hair loss, hyperkeratosis, impotence, increased urination, insomnia, macules, muscle cramps, myocardial infarction, palpitations, paresthesia, psychotic symptoms, purpura (vasculitis), shakiness, somnolence, spotty menstruation, sweating, syncope, urticaria. Treatment of Acute Cardiovascular Adverse Reactions: Whenever severe hypotension or complete AV block occur following oral administration of verapamil, the appropriate emergency measures should be applied immediately, e.g., intravenously administered isoproterenol HCl, levarterenol bitartrate, atropine (all in the usual doses), or calcium gluconate (10% solution). If further support is necessary, inotropic agents (dopamine or dobutamine) may be administered. Actual treatment and dosage should depend on the severity and the clinical situation and the judgment and experience of the treating physician.

OVERDOSAGE: Treatment of overdosage should be supportive. Beta-adrenergic stimulation or parenteral administration of calcium solutions may increase calcium ion flux across the slow channel, and have been used effectively in treatment of deliberate overdosage with verapamil. Clinically significant hypotensive reactions or fixed high degree AV block should be treated with vasopressor agents or cardiac pacing, respectively. Asystole should be handled by the usual measures including cardiopulmonary resuscitation.

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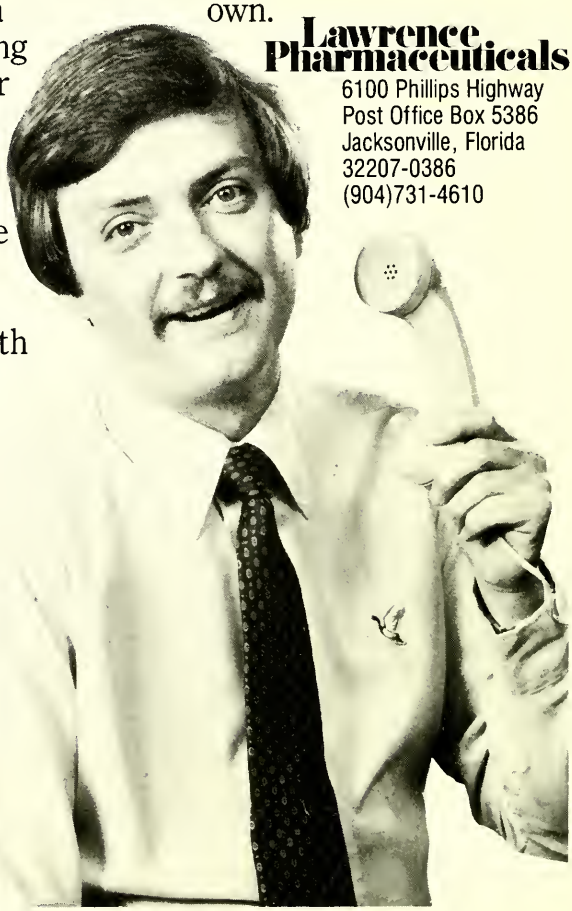

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Additions new members have been received after the Journal went to press. They will be acknowledged in the January 1987 issue.

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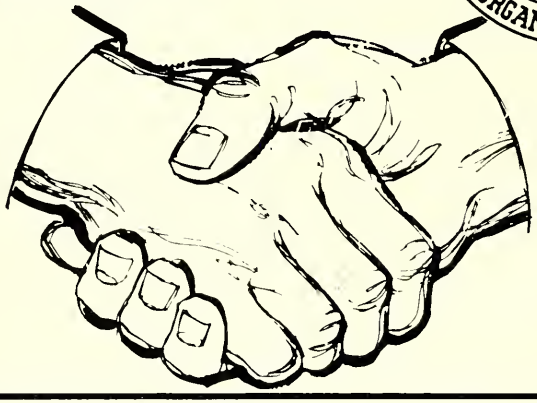

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AN ANALYSIS OF OVER THE COUNTER DRUG PRICES USING PRICE INDEX CALCULATIONS

by Allen Steen

This price index calculations project reveals the rise of OTC drug product prices over a twenty-year period from 1965 to 1985. One is able to compare the quantity and the prices of OTC drug products to each other by comparing them with a base reference figure.

In preparing this price index, the *American Druggist* "Open Call" issue of September 1984 was used in determining the top twenty OTC drug classes. Twenty OTC drug products, that appeared on the market in 1965, were chosen from these classes for this project. The 1965 edition of *Drugs Topics Red Book* was used to establish the reference year and the base reference index figure. Once these figures were established, 1967, 1969, 1971, 1973, 1975, 1977, 1979, 1981, 1983, and 1985 editions of the *Red Book* were used to list the price of each product of that year.

SUMMARY TABLE
(Base = 1965 = 100)

Item	1975 Index	1985 Index
Bayer 5 gr., 100	158.2	393.7
Tylenol 325 mg., 100	100.0	348.4
Ben Gay reg., 3 oz.	129.6	244.4
Kaopectate 8 oz.	107.1	188.5
Maalox 12 oz.	174.3	263.8
Mylanta 12 oz.	104.6	209.1
Pepto Bismol 16 oz.	133.1	297.6
Riopan 12 oz.	96.2	149.2
Lanacaine 2.5 oz.	121.2	186.8
Listerine 19 oz.	135.7	258.9
Actifed 100's	131.9	250.6
Contac 20's	107.3	262.9
Sudafed 100's	135.7	216.6
Murine 0.5 oz.	157.9	350.7
Visine 0.5 oz.	122.2	190.0
Preparation H 12's	133.6	290.6
Metamucil 8 oz.	118.1	271.8
Blistex 0.5 oz.	100.0	202.0
Dramamine 100's	110.9	501.3
Sominez 72's	121.9	256.9
Comsumer Price Index (CPI) (1967=100)	161.2	322.2
CPI Medical Care	168.6	403.1
CPI Rx Drugs	109.3	256.5

The index was then calculated by dividing each year's price by the 1965 price of the drug product and multiplying it by 100. The 1965 base index reference figure always starts at 100; if the price falls below the 1965 year's price that year's index figure will be below the 1965 base reference index figure of 100. *An Analysis of Price Trends for Drugs and Pharmacy Services Through the Calculation of Price Indexes* was used in determining the calculations and the format of this price index calculations project.

In conclusion, the price trend for most OTC drugs seems to be constant with little price increase before 1975. The inflation rate made a substantial increase about 1973–1975. One may notice a drastic increase in OTC drug products around the year of 1975; this is due to the inflation rate increase. From 1976 to 1985, OTC drug prices seem to have increased in price with a constant jump every other year. As one can see, the price for a certain amount of a product in 1985 exceeds the price paid for the same amount in 1965 by far.

PHI DELTA CHI INITIATES LEADERSHIP AWARD FOR YOUNG PHARMACISTS

A new award for leadership by a young pharmacist has been established by Phi Delta Chi Pharmacy Fraternity. To be awarded for the first time in 1987, the Albert B. Prescott Leadership Award will be given annually to a young pharmacist no more than 10 years into his or her career. The recipient will deliver a scholarly lecture on issues such as pharmacy as a profession, leadership, or future trends in pharmacy practice or education.

Albert B. Prescott was a maverick in the late 1800s because of his advocacy for an academic basis for pharmaceutical education. Founder and dean of the College of Pharemacy at the University of Michigan, Prescott nurtured his idea for nearly 25 years before the rest of the profession caught up with his vision. In 1900, Prescott was the first president of the American Association of Colleges of Pharmacy, and many schools date their founding from around the turn of the century. This chemist, educator, and leader of pharmacists was also instrumental in the founding of Phi Delta Chi at the University of Michigan in 1883, and he was the advisor to the

Continued on page 32

TOWARD BETTER COMPLIANCE

Noncompliance — the failure of patients to take their medicines as prescribed by the doctor — is a major health problem. It is estimated that no less than 20% of the patients who receive a prescription never have it filled. Or if they do, they never even take the first dose.

Noncompliance is not a new phenomenon. More than 2,000 years ago Hippocrates warned, "Keep watch also on the fault of patients which often makes them lie about taking things prescribed."

Things haven't changed all that much since Hippocrates' day, including a clear understanding of *why* people fail to take their medicine as the doctor prescribes. Theories abound, but answers are few. The fact remains, though, that each year millions of work hours are lost, billions of dollars in wages are lost, and thousands of hospital beds are filled, simply because people fail to take their medicines, or fail to take them properly.

The pharmaceutical manufacturing industry has assumed a number of initiatives in helping the health care community combat noncompliance. Using its vast scientific and technological resources, the main focus has been upon the development of medicines that are easier and more pleasant for patients to take.

Probably the most noteworthy of these developments has been to reduce the number of times a day the patient has to take medicine. In a great many cases, when in the past the dosage schedule was two, three or even four times a day, today's patients need take only one daily dose to receive the same therapeutic effect. Studies have shown that the fewer times a day a patient must take medicine, compliance will improve.

Pharmaceutical technology has replaced the huge "horse pill" with much smaller, slicker, easier-to-swallow tablets and capsules. That's a help, as is the idea of molding tablets into special shapes and colors. Many patients who must take several different medications each day can easily confuse "little white pills." That confusion vanishes when they are able to recognize a distinct shape or color.

Today, "taking your medicine" no longer means swallowing a bitter pill or a spoonful of some vile-tasting liquid. New flavoring technology make today's medicines far more palatable. It becomes, virtually, a pleasant experience for patients — especially children. They take their medicine willingly. And compliance improves.

Specific formulation techniques have also impacted on the problem of adverse side effects. Many of today's drugs produce less of them, or they are less severe — less to discourage compliance.

A more recent direction taken by industry has been the design of innovative drug delivery systems such as the transdermal patch. Only about twice the size of a bandaid, a single patch delivers medicine across and through the skin for as long as 24 continuous hours. More and more durgs are using this system. As a matter of fact, there are now once-weekly transdermal patches in use.

Questions as to *why* patient noncompliance persists continues to puzzle health care professionals. As science seeks answers to this complex issue, the pharmaceutical manufacturing industry will play its constructive role in combatting this serious health care problem.

PHI DELTA CHI

Continued from page 31

Alpha Chapter and the first honorary Brother of the Fraternity.

The recipient of the Prescott Leadership Award must:

1. Have entered the profession of pharmacy (i.e., graduated from pharmacy school) less than 10 years before nomination.
2. Have demonstrated exemplary leadership qualities as a student and young pharmacist indicative of someone likely to emerge as a major leader in pharmacy over the course of his or her career.

Nominations for the first Prescott recipient are now being accepted. These should be sent to the chairman of the selection committee, Lawrence C. Weaver, Ph.D., at the Pharmaceutical Manufacturers Association, 1100 15th Street, NW, Washington, DC 20005. The deadline for receipt of nominations is January 15, 1987. A copy of the nominee's curriculum vitae is requested.

Phi Delta Chi Pharmacy Fraternity comprises chapters at 48 colleges of pharmacy across the country. Nearly 33,000 men and women have been proud to call themselves Brothers of Phi Delta Chi and Leaders in Pharmacy. For more information about the Fraternity, contact the National Office at 2300 Ninth Street South, Suite 517, Arlington, VA 22204; 703/920-3700.

STRESS AND SEASONAL EFFECTS: NO HOLIDAY FOR ACNE

It's New Year's Eve, and your date for that party you've long anticipated is due to arrive shortly. As you are getting ready, a glimpse in the mirror reveals you've had a sudden acne flare-up. You panic.

Can this situation, experienced by millions, be avoided? Yes.

Thanks to recent advances in dermatology, and the availability of water-based cosmetics that can temporarily camouflage blemishes, acne flare-ups need not cause axiety. Dermatologists now have an arsenal of treatments for acne — such as antibiotics applied directly to the problem areas — which have proven highly effective.

For acne sufferers — teenagers and adults — the anticipation of special events around holidays such as New Year's, Christmas and Valentine's Day often exacerbate an acne flare-up. Outbreaks are also common just before an important exam, a job interview or a long-awaited social event.

The fall and winter months may cause acne flare-ups as well. A decrease in exposure to the sun's ultra-violet rays often leads to outbreaks.

"There are two main reasons for increases in acne during fall and winter — one is the seasonal change in climate and the other is stress," says Richard Dobson, M.D., chairman, Department of Dermatology, Medical University of South Carolina.

"Although the exact reasons are not known, small amounts of ultra-violet light help control acne, and the lack of exposure to the sun often causes acne to flare-up," explains Dr. Dobson. "At the same time, stress and anxiety typically increase with the return to school. What's more, the anticipation of special events during the holidays can also heighten the stress level."

Why does increased stress prompt acne flare-ups? If you're an acne sufferer and you're under heightened stress, your oil glands are more active. The result: an increase in the production of sebum (body oil), which can clog the skin canals and lead to acne.

Sebum production is controlled by the male androgenous hormones. Stress stimulates the adrenal glands to produce extra androgens, leading to the flare-up of acne. An immediate acne stress reaction is provoked by the body's lowered resistance. While stress-induced acne can occur almost immediately or over a period of weeks, the body's natural defenses can keep blemishes from developing for only so long.

"Almost every medical problem is affected by stress and acne is no different," says Dr. Dobson. "It's not uncommon for teenagers, just before an important exam or the night of a prom, to experience an acne flare-up. The same type of physiological experience can occur for adults as well. If an acne-prone adult is worrying about a job interview or an upcoming social function, such stress can trigger an outbreak of blemishes."

It is believed that acne victims suffer less from the skin disorder during the summer months. Vacations and periods of relaxation are generally less stressful and acne often subsides. In addition, sunshine may help dry up the excess oil that contributes to some acne conditions, and a suntan helps camouflage blemishes.

However, when the summer's over and things get "back to normal," so does the acne. This could be the "back-to-school syndrome," as described by Dr. Dobson. Dermatologists note that they tend to get most new patients for acne treatment just about the time school begins.

Physicians who specialize in skin care also see an increase in patients with acne problems just after the holidays. And this is more than coincidence: the holidays are often accompanied by changes in normal routines and increased anxiety, both of which can heighten stress.

"Acne does increase during the winter months and around the holidays," says Robert Auerbach, M.D., clinical associate professor, Department of Dermatology, New York University School of Medicine. "My personal feeling about why this occurs is that acne sufferers do not follow their normal health routines during this busy time, and simply stop their prescribed application of medication."

Help is available for adults and teenagers with acne, but physicians warn about waiting until the last minute before an important event to take preventative action. Severe cases — those that don't respond to over-the-counter treatments or cause scarring — warrant medical consultation.

Physicians say you *can* lessen the chances of an embarrassing flare-up prior to an important event, including that long-awaited New Year's Eve party. If you're concerned about an existing acne condition, experts suggest consulting a dermatologist to find out about treatments

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JUST HOW MUCH IS A CLINICAL PHARMACIST WORTH?

by Ronald Maddox, Dean
Campbell University School of Pharmacy

Not much if he spends all his time making rounds, advising doctors, and reading journals. Yes, these things are important — very important in fact, but unless the clinical pharmacist has constant contact with the physical pharmacy and firsthand knowledge of the product, he soon becomes a prima donna.

Unfortunately, there are very few job openings for clinical pharmacists with strictly advisory duties. Most of us are expected to earn our salaries with the "meat and potatoes" of delivering the proper medication to the proper patient at the proper time. Our dessert comes when we have proven our knowledge of drugs to the physicians sufficiently to "merit" consultations. Then, and only then, do we deserve to be consulted.

Many clinical pharmacists seem to be struggling to take over the physician's role. They even attempt to intrude on the diagnosis, the physician's primary function. This tendency smacks of egotism, in as much as the physician has spent literally years training himself to diagnose the patient's illness. It closely parallels the phenomenon of the physician prescribing medication for the patient. Since pharmacists have spent years learning almost exclusively about medications, I would hope they would stick with what they know best, and vice versa.

On the other hand, a clinical pharmacist can have a dramatic impact on patient care through his direct contact with the patients. His ability to discuss the patient's disease state knowledgeably helps him gain the patient's confidence. Confidence in the ability of the clinical pharmacist can inspire the patient to adhere to the drug regimen. Faith in the pharmacist can cause the patient to realize the importance of taking the medication properly. Little good ever came from the medication sitting in the bottle unused, and more than one patient has been "cured" by a sugar pill. If he believes the medication will help him, more than likely he will take it, and more than likely it will help.

Not only does the patient have respect for the clinical pharmacist's added expertise, the physicians and nurses are rapidly gaining respect for this new breed of pharmacist. The physician generally realizes what a vast amount of information on drugs and particularly drug interactions that he does not possess and could never be expected to; thus, he is fairly willing to share this responsibility with someone specializing in this area.

Last, but perhaps most outstanding, is the role of the clinical pharmacist in community practice. Here perhaps lies the greatest potential for expansion in the role for the pharmacist. The community pharmacist has more patient contact than any other health care individual. For this reason, the patient probably knows him better, feels more at ease, less rushed, and less in awe of his physician. He is more likely to talk openly and honestly in a relaxed setting. Most patients are actually afraid to ask their physician questions! They don't want to take up his time, or show how little they know, or are so confused by the small amount they have been told that they don't know where to begin.

What a fantastic opportunity for the clinical pharmacist to counsel these patients! What an opportunity to allow the patient to confide in him the symptoms that he won't mention to his physician because he fears the worst.

Just how much is a clinical pharmacist worth? For my money, he is the best buy around.

Reprinted from the
Georgia Pharmacy Journal, 1980

ACNE

Continued from page 33

available to you. While most cases can be controlled within a reasonable amount of time, they say you should plan accordingly since proper treatment does take time.

For more information about acne, The Upjohn Company is offering a pamphlet, "Answers To Questions About Acne," with some straight talk on an often misunderstood subject that separates myth from fact. For a free copy, send a stamped, self-addressed business envelope to:

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Continued on page 36

CLASSIFIEDS

Continued from page 35

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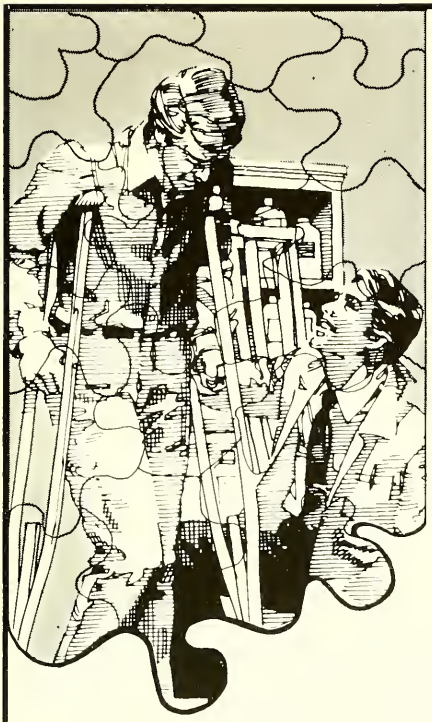
OBITUARIES

James M. Darlington

James M. Darlington, Winston Salem, died Friday, October 10, at the age of 87. A graduate of the Medical College of Virginia School of Pharmacy, he retired as president of O'Hanlon Watson Wholesale Drug Company in 1967. He was born in South Carolina, reared in Leaksville (now Eden), NC and lived in Winston Salem the past sixty years. He was a Life Member of the Traveling Members Auxiliary and served as local chairman of the NCPhA Convention in Winston Salem in 1954.

T.E. Holding III

Tommy Holding, Wake Forest, died Thursday, November 6, 1986 at Rex Hospital after an extended illness. Holding, a 1961 graduate of Samford University School of Pharmacy, was owner of T.E. Holding Drugs, and T.E. Holding Labs Inc. His Wake Forest Store was opened by his grandfather in 1888.



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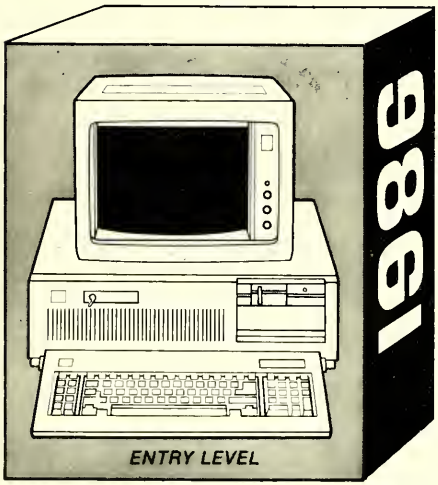

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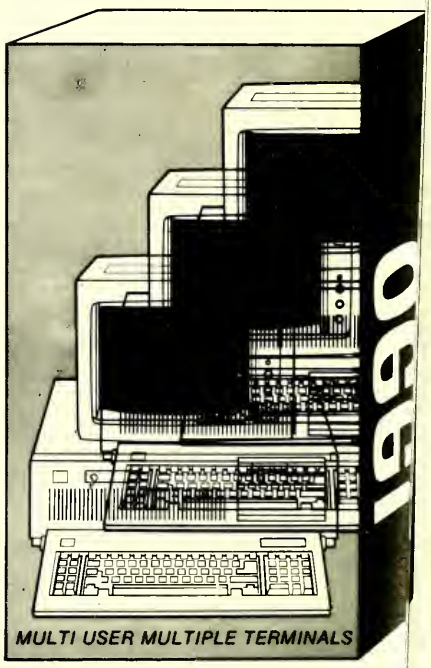

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